eligible applicant and shall include an agreement to:

(i) Provide without cost to the United States all lands, easements and rights-of-way necessary to accomplish the approved work; and

(ii) Hold and save the United States free from damages due to the requested work, and shall indemnify the Federal government against any claims arising from such work.

(4) The request shall be accompanied by:

(i) A statement of the reasons why the work cannot be performed by the applicant or the State government; and

(ii) Assurance by the applicant of compliance with Title VI of the Civil Rights Act of 1964, Pub. L. 88–352, 78 Stat. 241 (42 USC 2000d–2000d–4), and section 311, Pub. L. 93–288.

(d) *Requests by the State.* (1) In those instances where the required resolution by each applicant cannot be obtained on a timely basis to meet immediate needs, the Governor's Authorized Representative may submit a State request for direct Federal assistance which conforms to the requirements of (c) (3) and (4) for the Regional Directors's approval.

(2) Such State requests must be submitted within ten days after the date of the applicant's designation for public assistance. Applicants covered by the State request shall submit an appropriate request through the Governor's Authorize Representative in accordance with paragraph (c) of this section within 10 additional days. The time limits of this paragraph may be extended by the Associate Director.

(e) *Approval.*—(1) *State.* If the Governor's Authorized Representative concurs that the debris removal or emergency work is necessary and cannot be accomplished by the applicant, by another local government, or by the State, the request will be endorsed and forwarded to the Regional Director together with a statement of the reason why the State cannot provide the requested assistance.

(2) *Regional Director.* (i) If the Regional Director approves the request, a mission assignment will be issued to the appropriate Federal agency. The assignment letter to the agency shall define the scope of eligible work. Prior to execution of work on any project, a Damage Survey Report shall be prepared establishing the scope and cost of eligible work. The Damage Survey Report shall then be submitted to the Regional Director for approval. The Federal agency shall not exceed the limit on funding approved by the Regional Director without obtaining prior authorization.

(ii) If all or any part of the requested work falls within another Federal agency's statutory authorities and capabilities, the Regional Director shall not approve that portion of the work. In such case, the unapproved portion of the request will be referred to the appropriate agency for action.

(f) Time limitation for completion of work by a Federal agency under a mission assignment is three months after the President's declaration. Based on extenuating circumstance or unusual project requirements, the Regional Director may extend this time limitation.

(g) *Project management.*—(1) *Federal agency responsibilities.* The performing Federal agency shall ensure that the work is completed in accordance with the Regional Director's approved scope of work, costs and time limitations. The performing Federal agency shall also keep the Regional Director, the Governor's Authorized Representative, and the applicant advised of work progress and developments. The Federal agency is also responsible for obtaining any necessary permits or licenses and for compliance with applicable Federal, State and local laws and requirements. A final inspection report will be completed on all direct Federal assistance work. Final inspection reports will be signed by a representative of the performing Federal agency and the applicant's authorized agent. Once the final eligible mission assignment cost for an applicant is determined (including Federal agency overhead), it shall be included as an eligible cost in the applicant's project application [see § 205.113(b) Funding Limitations and § 205.114(f) Advances of Funds].

(2) *Applicant responsibilities.* The applicant shall assist the performing Federal agency in all support and local jurisdictional matters that a private owner would assume in a relationship with a performing contractor.

Dated: April 4, 1986.

Samuel W. Speck,

Associate Director, State and Local Programs and Support.

[FR Doc. 86–8478 Filed 4–17–86; 8:45 am]

BILLING CODE 6718–02–M

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44 CFR Part 205

Disaster Assistance; Subpart M (Hazard Mitigation)

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule.

SUMMARY: This subpart provide guidance for the implementation of section 406 of the Disaster Relief Act Amendments of 1974, (The Act). Section 406 requires that, as a condition of grant or loan assistance provided under the Act, State and local applicants shall repair damaged facilities in conformity with applicable codes, specifications and standards and in accordance with applicable standards of safety, decency and sanitation. As a further condition of assistance, State and local applicants are required to evaluate the hazards in the disaster areas and take appropriate actions to mitigate such hazards, including safe land use and construction practices.

DATE: Comment: DUES June 17, 1986.

ADDRESSES: Send comments to: Rules Docket Clerk, Office of General Counsel, Federal Emergency Management Agency, 500 O Street SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Laurence W. Zensinger, Office of Disaster Assistance Programs, Federal Emergency Management Agency, Room 714, 500 C Street SW., Washington, DC 20472, Telephone (202) 646–3681.

SUPPLEMENTARY INFORMATION: The Disaster Relief Act Amendments of 1974 included, for the first time in federal disaster legislation, at section 406, a requirement that recipients of assistance, as a condition of receiving such assistance, take measures to "mitigate" hazards in the presidentially declared disaster areas. Within the context of the legislation, the term "mitigate" is taken to mean "reduce" or "avoid" exposure or vulnerability to hazards on a long term basis.

The requirement to take actions to mitigate damages takes two forms in the wording of section 406 of the Act. First, section 406 requires that applicants undertake repair and reconstruction "in accordance with applicable standards of safety, decency and sanitation and in conformity with applicable codes, specifications and standards . . ." This clearly indicates a recognition by Congress that many facilities eligible for repair under the Act will be damaged because, to some extent, they were not orginally constructed in consideration of the hazards that may be present. There are many reasons why facilities may have not originally been built in recognition of hazards. First, maps and other technical information on the location and severity of hazards was not generally available when many public facilities were built on older urban areas. In addition, such things as beach erosion, removal of vegetation, changes in stream channels, or other long term alterations to the natural environment

have, in many cases, made facilities vulnerable to damage from flooding or mudslide threats that were not present when the facilities were initially constructed. Finally, many communities knowledgable of the potential effects of hazards within their jurisdictions have underestimated the economic impact of the hazards and therefore not considered them in their development decisions.

The second aspect of "mitigation" included under section 406 takes into consideration these potential problems and includes a requirement, therefore, that "as a further condition of any loan or grant made under the provisions of this Act, the State or local government shall agree that the natural hazards in the areas in which the proceeds of the grants or loans are to be used shall be evaluated and appropriate action shall be taken to mitigate such hazards, including safe land use and construction practices in accordance with standards prescribed or approved by the President . . ." Through this part of the law, Congress has introduced four important concepts into the disaster assistance process. First, State and local governments are required to "evaluate" the natural hazards in the areas where grants or loans are to be used. Congress clearly intended through this requirement that repair and reconstruction should be done, at a minimum, in full recognition of the degree of risk present in the disaster area, to the extent that this degree of risk can be known. The second concept involves taking "appropriate" actions to mitigate the hazards present. Use of the word "appropriate" indicates that mitigation measures must pass some test of reasonableness. Since the overall intent of section 406 is to minimize the potential for future damages, and therefore future costs for repair or replacement, it can be inferred that appropriate actions are those which balance the cost of the mitigation actions against the potential cost of continued damages if such measures are not taken. Underlying the Act is a clear recognition that some future damages can be avoided through reasonable and cost-effective measures, but that some mitigation measures may be more costly than the damages they are intended to prevent and therefore not appropriate. The third concept introduced is that, among those actions which may be considered appropriate in mitigating hazards, land use and construction practices should be given particular attention. Land use plans and building codes are generally adopted on a community wide basis and are long term approaches to addressing problems of hazard vulnerability. Finally, the President is authorized to prescribe hazard mitigation standards and approve such standards proposed by State or local governments.

Following enactment of the Federal Disaster Relief Act Amendments of 1974, FEMA's predecessor, the Federal Disaster Assistance Administration, undertook studies to identify the most feasible approach to carry out Federal responsibilities under section 406.

These studies lead to adoption, on November 8, 1979, of the regulations currently found at 44 CFR Part 205, Subpart M, Hazard Mitigation.

In dealing with the requirement to evaluate hazards and take mitigation actions as a condition of assistance, the existing regulations recognize that it would be impractical to provide assistance to applicants only after these conditions have been met. Instead, the existing rule established a process whereby States were required to prepare and submit, within 180 days following declaration of the disaster, a hazard mitigation plan as evidence of compliance with this section of the law. While this approach sacrifices some control that FEMA has over the expenditure of funds by making assistance available to applicants before all the conditions for that assistance have been met, it recognizes that the need to provide disaster assistance in an expeditious manner following a disaster is of primary importance. The following proposed rule also incorporates this concept (i.e. a plan as evidence of compliance with the requirements of section 406) but makes several important changes to improve implementation.

Since 1979, a number of factors have combined to necessitate a comprehensive revision of the current subpart M regulations. First, in 1980, the Office of Management and Budget issued a directive to eleven Federal agencies, including FEMA, requiring them to coordinate post-flood disaster assistance and recovery planning and to emphasize nonstructural flood hazard mitigation measures, to the greatest extent possible, as part of an effort to minimize Federal expenditures over the long term for flood disaster recovery assistance. An interagency agreement signed by these agencies created a process of post-disaster surveys and reports prepared by interagency teams, under the leadership of FEMA, which are intended to identify and recommend common federal approaches for recovery and mitigation actions. Since many of the disasters declared by the President result from floods, and since this interagency hazard mitigation team process impacts significantly on FEMA's recovery and mitigation programs, it is essential that the substantive and procedural requirements of both be closely coordinated. Also, with the creation of FEMA opportunities were presented for integrating section 406 requirements into overall emergency management functions of the agency which could not have been anticipated at the time the existing rule was being drafted. Finally, evaluation of the extent to which the present regulations have generated consistent, effective and meaningful hazard mitigation actions by State and local applicants has revealed some shortcomings in the current approach. These revised regulations are intended to address those shortcomings as well as incorporate the current role of hazard mitigation in FEMA's overall objectives of comprehensive emergency management.

Specifically, the revised section 406 regulations are intended to set forth clearer guidance on the scope and content of hazard mitigation plans. In the past, the plans FEMA has required under the authority of this section have varied greatly in quality and effect. One reason for this is that FEMA has never established criteria to enable determination of what constitutes an acceptable evaluation of hazards and acceptable actions to mitigate hazards. Without such criteria it has been impossible to determine whether or not States have made an adequate commitment to the mitigation of hazards, as prescribed by law. While, for the reasons stated above, it is impractical to withhold disaster assistance until applicants have complied with this section, some form of *quid pro quo* is required to ensure that the section 406 plan requirement is not viewed primarily as an afterthought. These revised regulations attempt to remedy the problems caused by unclear minimum criteria for hazard mitigation plans and the absence of clear connections between section 406 plans and the availability of current or future disaster and emergency assistance. The basic approach established by the revised regulations includes:

1. Focusing on the presence or absence of a State plan, program, strategy or policy for a comprehensive, multi-hazard approach to hazard mitigation on an on-going basis, and

2. Drawing heavily impacted and hazard-prone communities in the disaster area into the hazard mitigation planning process by requiring local

participation in the hazard mitigation planning process.

All the laws, programs, policies and activities within a State which contribute to decreasing or increasing vulnerability to natural hazards constitute its *de facto* hazard mitigation program. In response to a major disaster, FEMA will request the State to review these factors and determine whether or not the existing State laws, programs, or policies are adequate for controlling vulnerability to the hazards responsible for the disaster. Where State activities have not been analyzed in terms of their impact on hazard vulnerability, the proposed rule would require the State to draft a hazard mitigation plan which sets forth goals and objectives for improving State level management of hazards, and specify identifiable action items, timetables, and responsible agencies for achieving the goals and objectives. On the other hand, where States already have in place most of the elements of a comprehensive mitigation strategy, the proposed rule will require only a small scale mitigation program review and plan update, if necessary. This review will be intended to identify whatever minor adjustments are needed in the light of the recent disaster. In States with effective programs, very little additional work would be required, at the State level, to meet the hazard mitigation planning requirements of this proposed rule.

In the past, the hazard mitigation planning responsibilities of local government grant recipients under section 406 have not been clearly delineated. While the State is required to submit the plan as "evidence of compliance" with section 406, the requirements to take appropriate mitigation actions, including safe land use and construction practices, apply equally to local governments. Often, section 406 plans submitted by States have included recommendations made by the States to local governments to take certain actions to mitigate hazards. States, however, generally have limited authority to require such actions. At times States have made recommendations in hazard mitigation plans without the support or concurrence of the local governments to which they apply. Since the local governments have made no commitments to take these actions, and the States have no or limited authority to require them, the commitment to and chances of implementation are small. The proposed rule will require that local governments in the affected disaster areas be involved in the hazard mitigation planning process.

A weakness of the current procedures for administering section 406 requirements is FEMA's limited ability to use hazard mitigation requirements as a condition of assistance. The proposed rule addresses this issue in two ways. First, if no progress is being made by the State and local governments such that it appears unlikely that an acceptable plan or plan update will be forthcoming within 180 days, FEMA can suspend processing of applications until appropriate progress is demonstrated. Second, if States fail to submit a section 406 plan, or submit a plan which does not meet the minimum criteria of this proposed rule, the Regional Director may suspend the processing of public assistance project applications and withhold funding for any future disasters that occur in the areas covered by the plan.

The proposed rule sets forth, for the first time, specific criteria related to the contents of hazard mitigation plans. One of the key provisions of the proposed rule is the requirement to include proposed hazard mitigation measures that State and local agencies agree to undertake as a condition of assistance called "appropriate actions." These "appropriate actions" will be proposed by the State, subject to approval by the FEMA Regional Director, as part of the hazard mitigation plan. Appropriate actions represent the basic State and local management controls, such as building codes or design and construction criteria for public facilities, that are in general use around the nation. The purpose of requiring the hazard mitigation plans to include appropriate actions is to develop minimum standards for hazard mitigation in communities receiving federal disaster assistance. Appropriate actions identified by States and localities in hazard mitigation plans will be closely monitored by FEMA, and failure to implement appropriate actions in accordance with the hazard mitigation plan could jeopardize some forms of future disaster assistance.

The final major change proposed in this rule pertains to FEMA's approach to "disaster proofing" in the public assistance program. Disaster proofing is a category of eligible public assistance costs that can be used to help make damaged facilities more resistant to future damages as part of the process of reconstruction or repair. The current policy allows a small percentage of the total project cost (generally up to 15%) to be allocated for upgrading materials or modifying design of damaged facilities to make them less vulnerable. The current policy does not allow the applicant to contribute to the costs of disaster proofing by assuming any costs required above the 15%.

The proposed rule modifies this policy by, first, expanding the applicability of disaster proofing to any measure which would protect the damaged facility from future damages, whether or not such measure is an integral part of the repairs to the damaged facility and, second, allowing the applicant to contribute any amounts over and above the small percentage to be contributed by FEMA. This change in FEMA's approach to disaster proofing should promote greater creativity in the development of measures which will protect facilities subject to repetitive damages.

Environmental considerations

Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969 and the implementing regulations of the Council on Environmental Quality (40 CFR Parts 1500–1508), FEMA has prepared an environmental assessment for the issuance of proposed regulations implementing section 406 of the Act. This proposed rule is essentially procedural and is intended to clarify and add additional detail to existing procedures. FEMA has determined, therefore, that there will be no significant impact on the environment caused by issuance of this rule. As a result, an environmental impact statement will not be prepared. Copies of this assessment are available for inspection at: Federal Emergency Management Agency, Room 835, 500 C Street SW., Washington, DC 20472, Telephone (202) 646–4106.

Executive Order 12291, "Federal Regulations"

This rule is not a major rule within the context of Executive Order 12291. It will not have an annual impact on the economy of $100 million or more.

The rule will not have a significant economic impact on small entities, within the meaning of 5 U.S.C. 605 (The Regulatory Flexibility Act). Therefore, no regulatory analysis will be prepared.

List of Subjects in 44 CFR Part 205

Disaster assistance, Grant programs, Housing and community development.

PART 205—[AMENDED]

Accordingly, Title 44, Code of Federal Regulations, Part 205 is proposed to be amended as follows:

1. The authority citation for Part 205 is revised to read as follows:

Authority: 42 U.S.C. 5201; Reorganization Plan No. 3 of 1978; E.O. 12148.

2. Subpart M is revised to read as follows:

Subpart M—Hazard Mitigation

Subpart M—Hazard Mitigation

§ 205.400 General Introduction.

(a) *Purpose.* This subpart prescribes actions and procedures for implementing section 406 of The Disaster Relief Act of 1974 (Pub. L. 93–288), as amended, and prescribes Federal, State and local hazard mitigation responsibilities following the declaration of a major disaster or emergency by the President.

(b) *Content.* This subpart covers—

(1) The requirements for hazard mitigation planning and implementation that State and local grant recipients must meet as a condition for receiving disaster assistance loans or grants pursuant to Pub. L. 93–288 (the Act);

(2) The form and content of evidence of compliance State and local grant or loan recipients must provide showing that they have met such requirements;

(3) The process by which the Federal Emergency Management Agency (FEMA) will administer these requirements and provide technical assistance to applicants;

(4) The relationship between section 406 requirements and Interagency Flood Hazard Mitigation Teams required by the Office of Management and Budget directive of July, 1980, and;

(5) The criteria and procedures to be used by FEMA for funding hazard mitigation measures eligible for grant assistance under section 402 of the Act.

(c) *Requirements.* In enacting the Disaster Relief Act of 1974, Congress intended to provide assistance to alleviate the suffering and damage which result from disasters by, among other things, encouraging hazard mitigation measures, including safe land use and construction regulations, to reduce losses from disasters. The Act requires FEMA to place certain conditions upon any assistance provided under the Act. These conditions include—

(i) That State and local grant recipients shall agree that any repair or reconstruction financed under the Act be done in accordance with applicable standards of safety, decency and sanitation and in conformance with applicable codes, specifications and standards;

(2) That State and local grant recipients shall agree to evalaute the hazards in the impacted disaster areas and shall take appropriate action to mitigate such hazards in accordance with standards prescribed or approved by the President; and

(3) That State and local grant recipients shall provide evidence of compliance with paragraphs (c) (1) and (2) of this section as may be required by regulation.

(d) *Financial Assistance for Hazard Mitigation Planning.* The costs incurred by State and local governments for writing hazard mitigation plans prescribed under this subpart are the responsibility of the State and local governments. FEMA assistance available for this activity is limited to technical assistance. Nonetheless, there are a number of FEMA funded planning assistance programs that States and localities may use to help offset the costs of prescribed post-disaster hazard mitigation planning. For example, section 201(d) of Pub. L. 93–288 authorizes FEMA to make grants to states on an annual basis for the purpose of improving, maintaining and updating state disaster assistance plans. These plans, along with technical assistance authorized under Title II, are intended to develop comprehensive and practicable programs for preparation against disasters, including hazard reduction, avoidance and mitigation, among other things. States are encouraged to use this program (referred to as the Disaster Preparedness Improvement Grant Program) for the purposes of developing and implementing hazard mitigation plans prescribed by this subpart. Furthermore, states are encouraged to use financial resources provided by FEMA through other planning assistance programs included in the Comprehensive Cooperative Agreement or any other funding mechanism in use by FEMA to plan and carry out comprehensive, statewide multi-hazard mitigation actions.

(e) *Significant Commitment.* As a prerequisite to major disaster assistance under the Disaster Act, the governor of the affected State is required, among other things, to certify that for the current disaster, State and local government obligations and expenditures (of which State commitments must be a significant proportion) will constitute the expenditure of a reasonable amount of funds for alleviating the damage, loss, hardship or suffering resulting from the disaster. Funds allocated for the preparation of hazard mitigation plans and the coordination of State and local hazard mitigation actions prescribed by this subpart may constitute a portion of this significant State commitment.

(f) *Objections of Post-Disaster Hazard Mitigation Activities.* The objectives of section 406 of the Act are—

(1) To ensure that repairs and construction funded under the Act are protected from future damages to the greatest extent practicable limited only by consideration of engineering feasibility and cost-effectiveness;

(2) To use information and experience gained by the occurrence of a disaster to evaluate and improve where necessary State and local programs, policies, authorities and activities which affect the vulnerability of the built environment to damages from natural disasters;

(e) To incorporate mitigation consideration into all aspects of the recovery effort, and;

(4) To ensure that the appropriate resources of the Federal government are available to assist State and local governments in devising and carrying out programs to reduce or avoid vulnerability of the built environment to damages from natural hazards.

§ 205.401 Definitions.

As used in this subpart, the following definitions apply—

"Appropriate actions" are the actions state or local governments agree to take to mitigate hazards in the disaster area as a condition of receiving federal assistance. Appropriate actions are the hazard mitigation actions an applicant must agree to carry out in order to minimize hazard vulnerability based upon the degree of risk present in the disaster area.

"Disaster Proofing" means any modification or improvement in design of a facility, or system of which the damaged facility is a part, or any protective measure or technique, whether or not it is an integral part of a damaged facility, which will reduce the potential for damages to the facility.

"Federal Hazard Mitigation Coordinator" (FHMC) is the FEMA employee responsible for representing the agency for each major disaster declaration in carrying out the responsibilities of this subpart and coordinating post-disaster hazard mitigation actions with other agencies of government at all levels.

"Hazard Mitigation" is the process of systematically evaluating the nature and extent of vulnerability to the effects of

natural hazards present in society and planning and carrying out actions to minimize future vulnerability to hazards to the greatest extent practicable.

"Hazard Mitigation Survey Teams" are teams formed following the occurrence of a presidentially declared major disaster for the purpose of identifying post-disaster hazard mitigation opportunities and planning, recommending and coordinating the recovery and mitigation actions of all levels of government. Survey teams consist of State and appropriate local government representatives, and representatives of any Federal agencies which the Regional Director determines to be necessary to provide technical assistance or coordinate program activities. In the case of flood disasters, interagency hazard mitigation teams as defined in this subpart shall serve the purpose of hazard mitigation survey teams.

"Interagency Agreement for Post-Flood Hazard Mitigation Planning" is the interagency agreement signed by twelve federal agencies as a result of a directive issued by the Office of Management and Budget to these agencies to coordinate their post-disaster recovery assistance following presidentially declared flood disasters and to use this assistance to help in reducing any further damages through the most appropriate means available, including non-structural approaches.

"Interagency Flood Hazard Mitigation Teams" are teams consisting of representatives of the agencies signatory to the Interagency Agreement for Post-Flood Hazard Mitigation Planning which are activated following presidential flood disaster declarations for the purpose of recommending, planning and coordinating post-disaster hazard mitigation actions.

"Local Hazard Mitigation Coordinator" (LHMC) is the representative of local government who serves on Flood Hazard Mitigation Teams or Survey Teams and who is the primary point of contact with FEMA and other agencies in the planning and implementation of post-disaster hazard mitigation measures.

"State Hazard Mitigation Coordinator" (SHMC) is the representative of state government who serves on Flood Hazard Mitigation Teams or Survey Teams and who is the primary point of contact with FEMA and other agencies in the planning and implementation of post-disaster hazard mitigation measures.

§ 205.402 Responsibilities.

(a) *Purpose.* Programs to identify problems of hazard vulnerability and implement measures to avoid or reduce potential uneconomical disaster costs require the full partnership of Federal, State and local governments with appropriate consultation with the general public. This section identifies roles and responsibilities of FEMA, States and local participants in carrying out the requirements of section 406 of the Act.

(b) *FEMA.* The responsibilities of FEMA, acting through the appropriate Regional Director, in carrying out the requirements of this subpart and the Act are to—

(1) Include appropriate provisions for hazard mitigation in the FEMA/State Agreement for each major disaster declaration made by the President;

(2) Appoint a Federal Hazard Mitigation Coordinator (FHMC) for each disaster, in accordance with applicable FEMA policies, whose duties include;

(i) Ensuring that all FEMA disaster assistance actions are in compliance with 44 CFR Parts 9 and 10 and this subpart;

(ii) Leading or overseeing leadership of hazard mitigation survey teams, and, in the case of flood disasters, the Interagency Flood Hazard Mitigation Teams;

(iii) Obtaining and coordinating resources of other Federal agencies in support of FEMA's hazard mitigation responsibilities;

(iv) Serving as the point of contact with the State Hazard Mitigation Coordinator (SHMC);

(v) Monitoring and following up with State and local participants to ensure compliance with this subpart and implementation of agreed upon hazard mitigation measures;

(vi) Providing technical support to State and local participants in developing and carrying out their hazard mitigation programs;

(vii) Coordinating with the Regional Director's representative responsible for public assistance to ensure that appropriate conditions and standards approved by the Regional Director are incorporated into FEMA funded projects; and

(viii) Assuming responsibility for other hazard mitigation functions as necessary;

(3) Follow up with State and local grant recipients to recover Federal funding whenever an applicant fails to satisfy any conditions upon which approval of the grant was based;

(4) Make determinations as to whether documents, plans or reports submitted by State and local applicants constitute adequate evidence of compliance with section 406;

(5) Establish hazard mitigation conditions, including land use and construction requirements with general applicability throughout the impacted communities, as conditions for approval of FEMA grants and loans;

(6) Evaluate existing hazard mitigation plans and determine whether State and local applicants, in fulfilling the requirements of the subpart, shall either update existing hazard mitigation plans or develop new ones;

(7) Ensure that all Federal grant or loan recipients are aware of hazard mitigation requirements;

(8) Identify the need for and request or direct appropriate technical assistance from other Federal agencies required by FEMA to carry out satisfactorily its responsibilities under this subpart, in accordance with 44 CFR 205.151;

(9) Provide technical assistance to State and local governments in fulfilling the requirements of this subpart; and

(10) Conduct periodic review of State hazard mitigation activities and programs to ensure that States are adequately prepared to meet their responsibilities under the Act.

(c) *States.* The responsibilities that States are required to undertake following a disaster to meet the requirements of this subpart include:

(1) Appointing a hazard mitigation coordinator, who reports to the governor or his authorized representative, to serve as a point of contact with the FEMA hazard mitigation coordinator for all matters relating to Section 406 planning and implementation;

(2) Preparing and submitting, in accordance with the FEMA/State Agreement and the requirements of this subpart, a hazard mitigation plan(s) or updates to existing plans, as appropriate;

(3) Following up with local governments to assure that as a condition for any grant or loan under the Act, appropriate hazard mitigation actions are taken by local governments. This involves coordination of plans and actions of local applicants to assure that they are not in conflict with each other or with State plans; and

(4) Ensuring that the activities, programs and policies of all State agencies related to hazard vulnerability and management are coordinated and contribute to the overall lessening or avoiding of vulnerability to natural hazards.

(d) *Local Governments.* For the purposes of this subpart, the definition of local governments found at 44 CFR Part 205, Subpart A applies. Local governments are responsible for meeting the same requirements of section 406 of

the Act for hazard mitigation as States, including evaluating hazards and undertaking hazard mitigation measures. A hazard mitigation plan submitted by a State in fulfillment of the requirements of this subpart should address appropriate local hazard mitigation needs and measures. Local responsibilities include:

(1) Participating, along with the State and other appropriate local governments, in the process of evaluating hazards and adopting appropriate hazard mitigation measures, including land use and construction standards, as a condition of grants or loans under the Act;

(2) Participating in hazard mitigation survey teams, and interagency hazard mitigation teams, as appropriate; and

(3) Participating in the development of Section 406 plans, as appropriate, in conjunction with State hazard mitigation planning activities.

§ 205.403 Disaster Declaration Activities.

(a) *Purpose.* As part of FEMA's response to a governor's request for a major disaster declaration and, as part of the preliminary damage assessments conducted by FEMA, FEMA will evaluate information concerning the status of hazard mitigation efforts in the impacted states and localities. Through this evaluation FEMA will determine—

(1) The extent to which the disaster may have resulted from failure to carry out hazard mitigation actions that were a condition of federal assistance from previous disasters;

(2) The status of ongoing hazard mitigation programs and policies in the affected areas for use in tailoring the hazard mitigation conditions to be included in the FEMA/State disaster assistance agreement; and,

(3) The extent to which previously adopted hazard mitigation programs or actions were successful in reducing damages.

(b) *Program Evaluation:* As part of the process of reviewing requests for major disaster declaration, FEMA will conduct a hazard mitigation review. This review will consist, at a minimum, of evaluation of—

(1) The status of hazard mitigation plans or plan updates required as a condition of any previous disaster declarations for the same or similar previous disaster in the state. The review will determine whether any previous plans or plan updates were approved, not approved or not submitted in accordance with the requirements of this subpart by the state;

(2) The status of any appropriate actions which the state or localities agreed to undertake as a condition of previously provided disaster assistance. This includes evaluation of whether such appropriate actions have been taken or are in the process of being taken in accordance with the schedule established in the previous Section 406 plan of plan update;

(3) The presence or absence of a statewide comprehensive hazard mitigation plan, program or strategy, and

(4) Any other hazard mitigation information available to and considered relevant by the Regional Director or Associate Director, including the extent to which previously adopted hazard mitigation programs or actions may have contributed to reducing the impact of the disaster.

(c) *FEMA-State Agreement.* As part of the disaster assistance agreement for each major disaster declaration, the Regional Director shall include requirements, in accordance with section 406 of the Act, for taking appropriate actions to mitigate the hazards as a condition of federal assistance. The FEMA-State Agreement shall include the following required provisions:

(1) State and local grant recipients shall agree that repair or reconstruction financed under the provisions of the Act shall be in accordance with applicable standards of safety, decency and sanitation and in conformance with applicable codes, specifications and standards;

(2) State and local grant recipients agree that as a condition of any federal loan or grant, they will evaluate the hazards in the disaster area and shall make appropriate recommendations to mitigate such hazards;

(3) The State agrees to prepare and submit a hazard mitigation plan (or, hazard mitigation plan update) prepared in accordance with the requirements of § 205.405 of this subpart not later than 180 days after the date of the declaration of a major disaster to the Regional Director for approval;

(4) The State agrees to follow-up with local applicants to assure that as a condition of any grant or loan under the Act; appropriate hazard mitigation actions are taken by local applicants. This includes assuring that any appropriate actions included in the hazard mitigation plan or plan update which pertain to local applicants have been reviewed by the local applicants;

(5) The Regional Director agrees to make Federal technical assistance and advice available to support the planning efforts and actions of State and local applicants. In addition, the Regional Director may include other provisions or conditions in the agreement necessary to clarify responsibilities and meet the requirements of section 406 of the Act.

§ 205.404 Hazard Evaluation and Mitigation.

(a) *Hazard Mitigation Surveys.* Hazard mitigation surveys are performed immediately following the declaration of a disaster. The purpose of these surveys is to determine—

(1) The extent, nature and causes of damages which resulted in the disaster,

(2) Hazard mitigation measures that need to be incorporated into the response and recovery process to prevent uneconomical reinvestment in hazard prone areas and,

(3) Hazard mitigation programs and strategies that need to be improved or added to the normal operating procedures of Federal, State and local governments to minize future exposure to hazards in the disaster area(s). In preparing for hazard mitigation surveys, the FHMC and other appropriate members of the survey team should take part in preliminary damage assessments undertaken by FEMA when appropriate. Post-disaster surveys are an essential element of comprenhesive post-disaster mitigation since they create opportunities to influence recovery actions and provide direction to long term post-disaster mitigation planning.

(b) *Survey Teams.* Survey teams consist of—

(1) Representatives of Federal agencies that administer programs for facilities or activities that have been impacted by the disaster or that could contribute to accomplishing hazard mitigation through the recovery process;

(2) Representatives of impacted State and local jurisdictions;

(3) FEMA staff with relevant hazard specific program responsibilities (fire, earthquake, dam failures, flood, hurricane, etc.), and;

(4) Other non-governmental individuals with expertise deemed necessary or appropriate by the Regional Director. In the case of flood disaster, the interagency hazard mitigation team shall take the place of and perform the functions of the survey team. At a minimum, a survey team shall consist of a FEMA representative, and at least one State and a local representative, where feasible.

(c) *Survey Reports.* Within 15 days following a non-flood presidential disaster declaration, the FEMA team leader, in consultation with and with assistance from the other members of the hazard mitigation survey team, shall prepare a Hazard Mitigation Survey Report. This report shall, at a minimum, address the following:

(i) A general description of the nature and extent of damages and anticipated short and long term impacts;

(2) A description of the hazard which caused the damages, including any available information on frequencies, intensity, geographic extent, historical occurence;

(3) An overview of Federal, State and local land use or comprehensive development plans policies, programs and laws which are applicable to the impacted disaster area(s);

(4) An identification of potential hazard mitigation measures and options, including land use and construction practices that should be considered by all levels of government as part of the recovery and restoration process;

(5) Recommendations for redevelopment moratoria, conditions on grants or loans for restoring public facilities and infrastructure and any other measures necessary to insure that hazard mitigation opportunities are preserved and given adequate consideration, and

(6) Recommendations for long term considerations to be addressed by State and local applicants in the hazard mitigation plan prepared pursuant to this subpart. For flood disasters, the interagency hazard mitigation team report will take the place of the hazard mitigation survey report.

(d) *Activation.* Survey teams shall be activated for all presidentially declared disasters, except that, the Regional Director may determine not to activate a survey team when he/she determines that, due to the nature and extent of the disaster:

(1) Hazard mitigation opportunities are highly limited, and

(2) State and local hazard mitigation capabilities are adequate. Any determination not to activate a survey team shall be submitted to the Associate Director for concurrence.

(e) *Distribution of Survey Reports.* Survey reports shall be distributed in a timely manner to any agencies deemed appropriate by the Regional Director except that reports shall be distributed in all cases to the State and all local government units impacted by the disaster for use in their hazard mitigation planning activities. For flood disasters, hazard mitigation team reports shall be distributed in accordance with the provisions of the interagency agreement for post flood hazard mitigation planning and associated guidelines and procedures.

§ 205.405 Hazard Mitigation Plan Content.

(a) *Purpose.* The requirements for hazard mitigation planning set forth in this section are intended to complement the on-going land use management, building and development control practices of State and local governments. While the occurence of a disaster focuses attention on hazard problems and consequently creates an environment in which hazard mitigation measures are better understood and received, FEMA recognizes that the post-disaster setting is not the only or even the optimal time for managing vulnerability to hazards. State and local governments make decisions on a daily basis which influence vulnerability of the community to hazards. FEMA technical assistance and mitigation requirements, therefore, are oriented toward helping States and localities to develop hazard management capabilities and programs, as part of normal governmental functions, that will help to reduce current levels of hazard vulnerability and prevent new risks as States and communities grow and develop.

(b) *Requirements.* As a condition of any loans or grants provided under the Act, States and local governments shall—

(1) Evaluate the hazards in the areas in which the proceeds of the grants and loans are to be used;

(2) Take appropriate action to mitigate such hazards, including safe land use and construction practices and,

(3) Furnish evidence, in the form of a hazard mitigation plan or plan update prepared in accordance with the requirements of this subpart, that the hazards have been evaluated and appropriate action has been proposed or taken to mitigate such hazards.

(c) *Hazard Mitigation Plans.* A hazard mitigation plan is a logical or systematic identification of policies, programs, strategies and actions to be carried out by State and local governments to use the legal authorities, financial capabilities and political leadership available to reduce or avoid long term vulnerability to hazards. Hazard mitigation plans should include all the practicable measures available to limit hazard vulnerability. All States shall submit a hazard mitigation plan on behalf of the State and any appropriate local governments included in the disaster area within 180 days following the declaration of a presidential disaster unless—

(i) The Regional Director grants an extension not to exceed an additional 90 days, in which case the plan shall be submitted following the expiration of any extension or,

(2) The State and local governments currently have a written, published and officially adopted hazard mitigation plan or hazard mitigation element of a disaster assistance or comprehensive land use and development plan which, in the opinion of the Regional Director, substantially meets the requirements of this subpart.

(d) *Hazard Mitigation Plan Updates.* When the Regional Director determines that a State or local government has in effect a written, published and officially adopted hazard mitigation plan or hazard mitigation element of a disaster assistance or comprehensive land use and development plan which substantially meets the requirements of this subpart, the State or local government shall, as a condition of any financial assistance provided under the Act, review such plan(s) in the light of the current disaster and prepare an update to the existing hazard mitigation plan within 180 days following the presidential declaration of a major disaster, which evaluates the effectiveness of current and proposed mitigation measures and policies and adopts changes or improvements to current practices, where appropriate. Such plan updates shall be submitted to the Regional Director for review and approval.

(e) *Time Extensions.* In addition to the 90 day extension which may be granted by the Regional Director, any State may request additional time extensions required as a result of unusual circumstances. Requests for additional time extensions shall be submitted to the Regional Director who will forward such requests, along with his/her recommendation, to the Associate Director for approval.

(f) *Hazard Mitigation Plan Contents.* Hazard Mitigation plans or plan updates developed pursuant to section 406 or used by States and localities to meet the requirements of Section 406 shall include the following major elements:

(1) Evaluation of natural hazards in the declared disaster area. Hazard evaluation shall include—

(i) Any technical or descriptive information concerning the nature, severity, extent, frequency and historical occurrence of natural hazard events that can be expected to cause damage and loss to people and property, including assessment of the interrelationship of the various hazards to which the area is vulnerable, and

(ii) Analysis of hazard vulnerability trends and changes in vulnerability that can be expected to occur through time under current conditions of planning and hazard management. The hazard evaluation should incorporate and expand upon relevant information contained in the hazard mitigation survey report or interagency hazard

mitigation team report developed pursuant to § 205.405(c) (1) and (2) and should reference or incorporate any hazard analysis or hazard identification performed under any other FEMA funded program undertaken by the State or local government. Examples of the latter include hazard identification performed as part of a FEMA funded Hazard Identification/Capability Assessment/Multi-Year Development Plan (HICA MYDP) or FEMA funded hazard specific planning programs, such as landslide, hurricane preparedness or earthquake preparedness and mitigation programs;

(2) Description and analysis of current State/local hazard management policies/programs/capabilities. Many official policies or programs of State or local government influence development in hazard prone areas and contribute to either increasing or decreasing vulnerability to hazards. This analysis should review such things as—

(i) Land use planning and zoning practices;

(ii) Construction codes and building requirements;

(iii) Capital improvement programming;

(iv) Warning and evacuation systems;

(v) Hazard awareness and public information/education programs;

(vi) Public works programs for hazard control and damage prevention;

(vii) Fiscal policies; and

(viii) Any other laws, statutes or ordinances which affect public safety, protection of the environment or other issues related to hazard reduction, avoidance and mitigation. The analysis should determine the current effectiveness and adequacy of existing programs, policies and authorities for managing hazard vulnerability;

(3) Proposed hazard mitigation strategies, programs, and recommendations. Based upon the problems of hazard vulnerability defined in the hazard evaluation and the review of current programs, policies and capabilities for managing hazards, the plan shall propose a specific set of actions or measures for addressing each of the major current areas of need in the State or local hazard management program. For each of the functions or activities identified at § 205.405(e)(2) (i–viii), the plan or plan update should include proposed improvements, modifications or changes which would help to reduce or avoid vulnerability to hazards identified at § 205.405(e)(1). For each proposed new hazard mitigation strategy, program or action, the plan shall include an identification of—

(i) Anticipated completion dates or implementation schedules;

(ii) The Department, agency or official of State or local government responsible for implementation;

(iii) Anticipated costs of carrying out the recommendation, if any; and

(iv) The proposed source of funding.

(g) *Appropriate Actions.* Each hazard mitigation plan or plan update prepared and submitted in order to fulfill the requirements of this subpart shall identify one or more high priority recommendations contained in the plan or plan update which will be considered the minimum hazard mitigation actions the State or locality must take in order to have a measurable impact on reducing or avoiding the adverse effects of a specific hazard or hazardous situation. These appropriate actions should be drawn from the proposed hazard mitigation programs, strategies and recommendations contained in the plan in accordance with paragraph (f)(3) of this section. The purpose of appropriate actions is to prevent future uneconomic costs for disaster assistance. As such, failure on the part of a State of locality to carry out appropriate actions in accordance with procedures and schedules established in the hazard mitigation plan, will result in the withholding of federal financial assistance for any future disaster damages which the Regional Director determines would not have occurred if the appropriate hazard mitigation actions had been taken.

(h) *Exception To The Requirement For Appropriate Actions.* FEMA may decide, based upon the nature and severity of any presidentially declared disaster, to waive the requirement that State and local applicants include appropriate actions in any hazard mitigation plan or plan update submitted in accordance with the requirements of this subpart. To obtain a waiver of this requirement, the State or local applicant must submit a request in writing to the Regional Director stating the reasons why a waiver is warranted. A waiver of this requirement will be justified if—

(1) There can be considered no reasonable likelihood, based upon the best technical information available, that the events which caused the disaster could occur again within a time frame or with a degree of severity that would justify the economic cost of reasonably available hazard mitigation measures, or

(2) There are no reasonably available techniques or actions which would prevent or reduce the damages should the events which caused the disaster occur again. Upon receipt of a request for a waiver of the requirement to identify appropriate actions as part of the hazard mitigation plan or plan update, the Regional Director shall review such request and make a recommendation to the Associate Director for final decision. The Associate Director shall notify the Regional Director in writing of his/her decision.

§ 205.406 Hazard Mitigation Plan Development and Approval.

(a) *Purpose.* This section sets forth procedures for ensuring that hazard mitigation plans or plan updates developed pursuant to this subpart are prepared in a timely manner following the declaration of a major disaster and that such plans reflect and incorporate, to the greatest extent possible, previous information and evaluations which will minimize work effort. It also includes standards for FEMA technical assistance and review and approval of hazard mitigation plans and plan updates.

(b) *Scoping Meeting.* Within 45 days following the declaration of a major disaster, the FHMC will hold a meeting with the SHMC and appropriate LHMC's for the purpose of developing a timetable and scope of work for the hazard mitigation plan or plan update. Topics to be covered at the scoping meeting include;

(1) A detailed briefing by the FHMC on the purpose and requirements of section 406, this subpart, and the hazard mitigation plan or plan update;

(2) Key hazard vulnerability or hazard mitigation issues that should be addressed by the hazard mitigation plan or plan update, including significant hazards and potential appropriate actions to be included in the plan, if any;

(3) The nature and extent of local applicant involvement in development of the plan or plan update, including—

(i) The extent to which the plan or plan update will focus upon State versus local hazard mitigation needs and actions, and

(ii) The division of responsibility and coordination required for development of the plan or plan update between the State and local applicants;

(4) A proposed timetable for development of the plan and interim outputs, including;

(i) Scheduling of technical assistance and progress review meetings;

(ii) State and local review and approval requirements and;

(iii) Dates for delivery, FEMA review/approval and publication and distribution by the State of the final plan or plan update. The SHMC should invite to the scoping meeting representatives of any other State agencies involved with public works, natural resources,

transportation or emergency management that, due to their mission, would appropriately be involved in the planning and implementation of hazard mitigation measures.

(c) *Specific Hazard Mitigation Projects.* At the scoping meeting Federal, State and local hazard mitigation coordinators should identify any specific hazard mitigation project actions that require further investigation as part of the Section 406 planning process or that should be initiated immediately as part of the disaster recovery process. Specific hazard mitigation projects will be drawn from—

(1) Interagency hazard mitigation team reports or survey reports;

(2) Flood plain management and hazard mitigation reviews performed as part of disaster survey reports, and

(3) Any other background information obtained from damage assessments or field reconnaissance. To the extent possible, federal agencies and State and local applicants should attempt to utilize the recovery resources available from all sources to implement identified specific projects as part of the recovery process.

(d) *Progress Reporting and Review.* The FHMC will monitor the development of hazard mitigation plans or plan updates to ensure that adequate progress is being made in conformance with the established schedule. Reporting by the State should be in the form of a brief written progress report submitted bimonthly following declaration of the disaster by the SHMC to the Regional Director. The Regional Director may schedule, in consultation with the State, other meetings or reports he/she deems necessary to ensure adequate monitoring. If, at any time during the development of the hazard mitigation plan or plan update, the Regional Director determines that the State or local applicants are not making adequate progress in developing the plan relative to established time schedules, he/she may, with the concurrence of the Associate Director, suspend payments or processing for any public assistance projects currently under consideration until hazard mitigation planning is on schedule. In suspending the processing of public assistance grant applications or payments, the Regional Director shall notify the State of his/her decision to do so and shall indicate what specific progress in development of the hazard mitigation plan is required in order to resume processing of grant applications and payments.

(e) *Technical Assistance.* The Regional Director, through the SHMC, will provide technical assistance to eligible grant applicants for planning and implementation of specific hazard mitigation projects or development of hazard mitigation plans and plan updates. The Regional Director may also provide mission assignments to federal agencies for the purpose of obtaining specialized kinds of technical assistance that would not otherwise be available to State or local applicants for development of hazard mitigation plans and plan updates.

(f) *Plan Certification.* In addition to the requirements contained in § 205.405 of this subpart, all hazard mitigation plans or plan updates forwarded to the Regional Director for approval as evidence of compliance with section 406 of the Act shall be signed and certified by the governor or his authorized representative as an officially adopted plan or policy of the State. In addition, if a hazard mitigation plan or plan update includes actions which will be the responsibility of substate or local jurisdictions to carry out, the plan or plan update shall include a description of the extent of local participation in the planning process.

(g) *Plan Approval.* Upon receipt of a hazard mitigation plan or plan update, the Regional Director shall acknowledge in writing such receipt to the governor or the appropriate agency or representative of State government. Within 45 days of receipt of the plan, the Regional Director shall provide written comments to the State with a determination of whether or not the plan satisfies the requirements of this subpart. If the plan or plan update satisfies the requirements of this subpart, the written comments to the State should include indication that the plan or plan update is approved. If the plan or plan update does not meet the minimum requirements of this subpart, it will not be approved and the Regional Director shall provide to the State in writing specific information concerning the portions of the plan or plan update that must be modified, expanded or improved in order for the plan to be approved. If the plan or plan update is not approved, the Regional Director, after consultation with the Associate Director, shall notify the Governor of his/her authorized representative in writing that the State has 30 days in which to bring the plan or plan update into compliance with this subpart, after which time—

(1) The processing of all pending public assistance grant applications or payments for the presidential disaster declaration as a result of which the unapproved hazard mitigation plan or plan update has been prepared may be suspended pending the correction of deficiencies in the plan, and

(2) No new public assistance grant applications will be accepted for any subsequent presidential disaster declarations in the disaster area covered by the unapproved plan. The prohibitions of § 205.406(g) (1) and (2) shall be removed upon submittal by the State of a hazard mitigation plan or plan update which meets the requirements of this subpart and is approved by the Regional Director.

(h) *Appeals.* Appeals may be made to the suspension of assistance for failure to develop or submit a hazard mitigation plan in accordance with the requirements of this subpart. Such appeals shall be made in accordance with the procedures and criteria for appeals found at 44 CFR part 205, Subpart H.

(i) *Implementation and Monitoring.* From time to time, but not less than annually, FEMA will review State and local progress in the accomplishment of actions, recommendations or strategies contained in the approved hazard mitigation plan or plan update. The Regional Director may require the State or local applicants to provide progress reports on the implementation of hazard mitigation actions as necessary. If, as a result of any review of progress, the Regional Director, in consultation with the Associate Director, determines that any appropriate action contained in an approved hazard mitigation plan has not been implemented in accordance with the plan and its established time schedule, he/she may, after providing 30 days notice in writing of the intention to do so—

(1) Suspend processing of applications for assistance under section 402 of the Act from previous disaster declarations where the restored facilities would be at risk for failure to carry out the appropriate actions included in the plan that are not on schedule until such time as the appropriate actions are on schedule or completed, and

(2) Notify the State that no future applications for assistance under section 402 for any subsequent presidential disaster declarations will be approved for the facilities and in the area(s) covered by the appropriate actions that have not been carried out in accordance with the plan.

(j) *Amendments to Hazard Mitigation Plans.* The State may propose to the Regional Director at any time amendments to hazard mitigation plans or appropriate actions submitted in fulfillment of the requirements of this subpart. Such proposed amendments shall include a brief explanation of the reasons for the amendment. The Regional Director shall provide his/her

approval of amendments to the State in writing within 45 days of receipt of a request, and shall notify the Associate Director of any amendments approved.

§ 205.407 Funding Hazard Mitigation Measures.

(a) *Purpose.* Eligible costs for the reconstruction of damaged public facilities eligible for assistance pursuant to section 402 of the Act are generally limited to the costs of reconstructing to the predisaster design of the damaged facility, and in accordance with currently applicable codes, specifications and standards. In many cases, however, permanent repairs, alterations, or new construction to predisaster design may not result in facilities or structures which are safe from identified hazards. Alternate actions available include relocation to non-hazard prone areas, restoration in conformance with updated construction practices or standards, restoration in conjunction with measures or improvements which will make the facility less prone to subsequent damage (disaster proofing measures) or withholding of federal funding for the proposed work. This section covers criteria for funding disaster proofing measures in excess of the cost of repairing facilities in accordance with their predisaster design and in accordance with applicable codes, specifications and standards.

(b) *Disaster Proofing.* In restoring damaged or destroyed facilities with grant assistance for permanent work under section 402 of the Act, the Regional Director may authorize disaster proofing not required by applicable codes, specifications and standards when in the public interest. Disaster proofing consists of any modification or improvement in design of a facility or system of which the damged facility is a part, or any protective measure or technique, whether or not it is an integral part of the damaged facility, which will reduce the potential for future damages to the facility. In approving requests for disaster proofing, the Regional Director shall require that the following criteria be met:

(1) The disaster proofing measures must be judged by the Regional Director to be effective in substantially alleviating or eliminating recurrence of damage done to the facility by the major disaster,

(2) The measures must be feasible from the standpoint of sound engineering and construction practices,

(3) The measures must be cost-beneficial in protecting the federal investment, meaning that the total costs of the measures must be less, over the useful life of the structure (using a discounted rate), than the future damages that can be reasonably anticipated; further, the measures must be cost-effective, meaning that they must be less costly overall than any other measures that would be eligible as disaster proofing;

(4) The measures must be consistent with applicable NFIP standards (44 CFR Part 59, et seq.), Floodplain Management Regulations (44 CFR Part 9), and (where applicable), Environmental Considerations (44 CFR Part 10); and

(5) The cost to FEMA for disaster proofing measures shall not exceed a small percentage of the eligible project cost. The applicant may contribute any amount necessary to completely fund any disaster proofing measure that meets the other criteria of this paragraph.

(d) *Project Administration.* As a condition of approval of a project application for any project funded pursuant to Section 402 of the Act, and subsequently for approval of a voucher for final payment, the Governor's Authorized Representative and the Regional Director shall require documentation of required hazard mitigation measures, including compliance with applicable land use regulations and construction standards. In making final inspection reports, Federal and State inspectors shall verify compliance by the applicant with approved hazard mitigation standards.

Dated: April 4, 1986.

Samuel W. Speck,

Associate Director, State and Local Programs And Support.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 179

Irradiation in the Production, Processing, and Handling of Food; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 81N-0004]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to permit additional uses of ionizing radiation for the treatment of food. These regulations: (1) Permit manufacturers to use irradiation at doses not to exceed 1 kiloGray (kGy) to inhibit the growth and maturation of fresh foods and to disinfect food of arthropod pests, (2) permit manufacturers to use irradiation at doses not to exceed 30 kGy to disinfect dry or dehydrated aromatic vegetable substances (such as spices and herbs) of microorganisms, (3) require that foods that are irradiated be labeled to show this fact both at the wholesale and at the retail level, and (4) require that manufacturers maintain process records of irradiation for a specified period and make such records available for FDA inspection. These regulations are promulgated on the agency's initiative and are necessary to permit the safe use of ionizing radiation. This document responds to comments on the February 14, 1984, proposed rule (49 FR 5714).

DATES: Effective April 18, 1986; objections by May 19, 1986.

ADDRESS: Written objections and request for a hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORAMTION CONTACT: Clyde A. Takeguchi, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Under section 409 (b) and (d) of the Federal Food, Drug, and Cosmetic Act (the act), the Secretary may approve a food additive petition from an interested person or may propose the issuance of a food additive regulation upon the Secretary's own initiative (21 U.S.C. 348 (b) and (d)). It is less common for FDA, acting as the Secretary's delegate, to propose and then establish a regulation itself, than to respond to a sponsor's petition. In the case of food irradiation, FDA had, before 1981, approved several food additive petitions for the use of various sources of radiation on certain foods and food-packaging materials (21 CFR Part 179). Subsequent to these approvals, an FDA committee evaluated testing criteria that would be necessary to support the safety of food irradiation for various uses.

In the **Federal Register** of March 27, 1981 (46 FR 18992), FDA published an advance notice of proposed rulemaking that announced the availability of the Bureau of Foods' (now the Center for Food Safety and Applied Nutrition) Irradiated Food Committee (BFIFC) Report (Ref. 1), which outlined a course of action for assuring the safety of irradiated foods, and requested comments on the overall approach.

In the **Federal Register** of February 14, 1984 (49 FR 5714), FDA published a proposed rule that would: (1) Establish general provisions for food irradiation, (2) permit the use of food irradiation at doses not exceeding 1 kiloGray (kGy) (100 kilorads; 100 krad) [1] for inhibiting the growth and maturation of fruits and vegetables and for insect disinfestation of food, (3) allow irradiation to be used for microbial disinfection of certain dried spices and dried vegetable seasonings at a dose not to exceed 30 kGy (3 Mrad), (4) eliminate the current irradiated food labeling requirements for retail labeling, and (5) replace the current sections (21 CFR 179.22 and 179.24) dealing with the irradiation of food with new §§ 179.25 and 179.26 (21 CFR 179.25 and 179.26). The proposal responded to comments on the advance notice of proposed rulemaking.

Apart from that ongoing rulemaking, FDA has approved a number of food additive petitions to provide for the safe use of gamma radiation at doses up to 10 kGy (1 Mrad) to control insect infestation and microbial contamination in dried herbs, spices, and vegetable seasonings (48 FR 30613, July 5, 1983; 48 FR 46022, October 11, 1983; 49 FR 24988, June 19, 1984; 50 FR 15415, April 18, 1985) and in dry enzyme preparations (50 FR 24190, June 10, 1985). FDA also issued a final rule on July 22, 1985 (50 FR 29658) which amended 21 CFR 179.22(b) in response to a petition to provide for the safe use of gamma radiation at doses up to 1 kGy (100 krad) to control *Trichinella spiralis* in pork.

The act requires that a food additive, including a source of radiation used to process food, be shown to be safe under the proposed conditions of use before use of the food additive can be approved. That is, the agency must be assured with reasonable certainty that no harm will result from irradiation of food. A source of radiation is specifically defined as a food additive in section 201(s) of the act (21 U.S.C. 321(s)). The Senate report on the Food Additives Amendment of 1958 made clear that "[s]ources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term 'food additive' as defined in this legislation." S. Rept. 2422, 85th Cong., 2d Sess. 63 (1958).

Section 409 of the act lists the criteria which must be considered by the agency before a food additive regulation is issued. The statute does not prescribe what safety tests should be performed but leaves that determination to the discretion of scientists. The definition of safety, as drawn from the legislative history of the Food Additives Amendment of 1958, has been codified in 21 CFR 170.3(i) as follows:

(i) "Safe" or "safety" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended condition of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any

[1] The Systeme Internationale (SI) unit for expressing the amount of absorbed radiation dose is the Gray (joules/kilogram, abbreviated GY). An older unit commonly used is the rad. The equivalent value in rads (100 rad=1 Gy) will be enclosed in parentheses when referring to the amount of absorbed radiation. The prefixes kilo (k) and mega (M) represent a thousandfold and a millionfold, respectively. Thus, kilorad means a thousand rads and a megarad means a million rads.

chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

In passing the Food Additives Amendment of 1958, Congress recognized that it is impossible to establish with complete certainty the absolute harmlessness of any chemical substance. The concept of safety used in the amendment involves reducing uncertainty about the safety of an additive to the point where the agency can reasonably conclude that no harm will result from its proposed use.

This objective can be achieved in a variety of ways. To determine whether consumption of a substance is safe, the agency considers the amount and identity of the substance ingested in light of what is already known regarding its toxicity. Ordinarily, animal feeding tests are essential for assessing toxicity of a substance. Not all situations require the same amount or type of testing, however, to determine whether use of an additive is safe. The degree of effort expended in reducing uncertainty about the safety of an additive must relate in some way to the likelihood that use of the additive poses a potential health risk to the public. Testing that is unlikely to provide information that would reduce uncertainty regarding safety should not be required. To do otherwise would waste scarce scientific resources that could be used for more productive purposes.

II. Comments

The agency received over 5,000 comments on the proposal. Many of the comments simply stated opinions for or against permitting food irradiation or requiring special labeling but identified no substantive issues to which the agency can respond. For example, some comments expressed concern that food might become radioactive, but none provided factual support. Other comments acknowledged that irradiation of food will not make the food radioactive. The agency believes that the proposal adequately addressed the issue of induced radioactivity in food (see 49 FR at 5716). Because no evidence has been submitted to contradict FDA's finding that the irradiation of food does not cause the food to become radioactive, no further discussion of this issue is necessary.

Many of the comments were concerned about the formation and the safety of radiolytic products, and the effect of irradiation on nutrients in food. A majority of those comments stated that more studies were needed because the long-term effects of these radiolytic products have not been ascertained with enough certainty to justify the conclusion that the use of irradiation is safe. The substantive comments and FDA's response to each are discussed below.

A. Safety

Before responding to the substantive comments relating to safety, the agency believes it would be useful to explain again its safety assessment of food irradiation and its conclusions concerning the safety of foods irradiated in compliance with this regulation. A summary of FDA's position on safety is set forth below.

In the proposed rule, the agency stated "* * * that the safety of food irradiation below 1 kGy (100 krad) has been established * * * because: (1) Irradiation will not make the food radioactive, and thus cannot expose the consumer to radiation; (2) the chemical differences between irradiated foods processed at these doses and nonirradiated foods are too small to affect the safety of the foods; (3) food irradiated at doses up to 1 kGy (100 krad) will have the same nutritional value as similar foods that have not been irradiated; and (4) the balance between microbial spoilage organisms and pathogenic organisms is not adversely affected by radiation doses below 1 kGy (100 krad)" (49 FR 5718).

The agency has followed the same general procedures in the development of regulations for the use of sources of radiation as are followed in the development of regulations for other food additives. Under the act, the agency's primary responsibility is to determine that the additive is safe under the proposed conditions of use. Since the 1960's when the first petition for the treatment of food with radiation sources was submitted, the agency has been confronted with the question of what test procedures are appropriate to establish reasonable certainty of no harm for use of radiation sources in the treatment of food. In the absence of adequate data on the chemical changes in food treated with radiation and information on the nutritional quality of such food, FDA concluded that petitioners should submit long-term animal feeding studies to demonstrate the "wholesomeness" of the irradiated food. In those instances where petitioners have provided adequate chemical and nutritional data to the agency, FDA has not required petitioners to submit long-term animal feeding studies. For example, FDA has issued regulations authorizing the use of x-rays for inspection of food, microwaves for heating food, and ultraviolet radiation for treating food based on chemical analyses (see 21 CFR 179.21, 179.30, and 179.39, respectively).

In 1979, FDA established its Bureau of Foods Irradiated Food Committee (BFIFC) to review the existing agency policy concerning the irradiation of foods. BFIFC's main task was to make recommendations regarding the establishment of those toxicologic testing requirements appropriate for assessing the safety of irradiated foods. BFIFC's recommendation focused on making the degree of testing compatible with the potential risk as indicated by the level of anticipated human exposure. BFIFC recognized that safety assessments of irradiated food should be based on: (1) Projected levels of human exposure to the food; (2) estimates of the identify, amount, and potential toxicity of new chemical constituents generated in the food by the irradiation process; and (3) state-of-the-art sensitive toxicological tests. BFIFC completed its review and submitted its final report in July 1980 (Ref. 1).

BFIFC recognized that no single approach provided sufficient data to estimate the percentage of food consumption that might consist of irradiated food. Hence, in projecting human exposure to irradiated food, BFIFC used estimates of total food consumption, dietary items proposed for irradiation, and the percent of each dietary item which may be irradiated. Using a rough estimate based on these factors, BFIFC suggested that as much as 40 percent of the total diet could be irradiated, but anticipated that actual human exposure would not exceed 10 percent of the diet.

Further, the committee considered those chemical constituents generated by irradiation, also known as radiolytic products. BFIFC assumed that some radiolytic products may be unique to irradiated foods, and created the term "unique radiolytic products" (URP's) to mean substances not known to be present in nonirradiated food. However, BFIFC recognized that scientists do not know the extent to which these substances, although characterized as URP's, may actually be present as common constituents of the human diet.

BFIFC reviewed the available literature dealing with radiation chemistry, the identification and quantification of substances produced in foods as a result of irradiation, and found that the amount of radiolytic products generated is primarily dependent upon the amount of energy

absorbed by the food. Based on data showing how much chemical change is likely to be caused by a given amount of radiation energy, BFIFC concluded that irradiation of food at 1 kGy (100 krad) would generate approximately 30 parts per million (ppm) of radiolytic products. Experiments have shown that very few of these radiolytic products are unique to irradiated foods; approximately 90 percent of the radiolytic products identified by BFIFC are known to be natural components of food (Ref. 1). BFIFC found the remaining 10 percent of the radiolytic products to be chemically similar to known natural food components. Because of this chemical similarity, those radiolytic products are likely to be toxicologically similar also. Because natural components of food are not well characterized at the parts per million level, some radiolytic products assumed by BFIFC to be unique may actually be natural components of foods. However, even if 10 percent of the radiolytic products are unique, their cumulative concentration in food irradiated at 1 kGy (100 krad) would be only 3 per million, one-tenth the concentration of 30 parts per million for all radiolytic products. Moreover, the concentration of any single URP will probably be less than 1 part per million for food irradiated at 1 kGy (100 krad). Because different portions of a food being irradiated will receive different doses, the average radiation dose absorbed by the food will necessarily be less than the maximum permitted dose. Therefore, the concentration of URP's generated in food from irradiation should be even lower than the upper bound estimate calculated by BFIFC.

BFIFC concluded that because of the extremely low potential concentration of individual URP's in foods irradiated at doses below 1 kGy (100 krad), and because any URP's are likely to be toxicologically similar to other food components, it would be virtually impossible to detect potential toxicological properties of these substances. The current state-of-the-art toxicity tests are not sensitive enough to detect the potential toxicity of URP's at these low levels unless the URP's are far more potent than experience in the radiation chemistry of foods and in toxicology would suggest.

Because the potential concentration of URP's in irradiated food is low, BFIFC concluded that food irradiated at doses not exceeding 1 kGy (10 krad) is wholesome and safe for human consumption, even where the food that is irradiated may constitute a substantial portion of the diet. Consequently, the committee recommended that foods irradiated at doses below 1 kGy (100 krad) be considered safe for human consumption without the requirement of toxicological testing. BFIFC based this recommendation on radiation chemistry and on the anticipated low levels of human exposure to any URP's generated in irradiated foods.

The committee further concluded that a food (e.g., nutmeg) that comprises only a small fraction of the human diet (i.e., no more than 0.01 percent of the diet) and that is irradiated at doses up to 50 kGy (5 Mrad) would necessarily contribute far fewer radiolytic products to the daily diet—approximately 20 times less—than a food representing a significant fraction of the diet (e.g., 10 percent) irradiated at 1 kGy (100 krad). Consequently, BFIFC recommended that foods comprising no more than 0.01 percent of the daily diet and irradiated at 50 kGy (5 Mrad) or less also be considered safe for human consumption without toxicological testing. BFIFC based this recommendation on radiation chemistry and the anticipated low levels of human exposure to any URP's generated in irradiated foods.

The agency agreed with the scientific rationale and conclusion reached by BFIFC that an adequate margin of safety could be demonstrated for irradiated foods without the requirement of toxicological testing and adopted its recommendations concerning the safety of foods irradiated at the proposed dosage levels (March 27, 1981; 46 FR 18992).

Subsequently, in 1981, FDA's Bureau of Foods established the Irradiated Foods Task Group to review all available toxicological data concerning foods treated by irradiation. The major objectives of this Task Group were to compile and summarize the toxicology data pertaining to irradiated foods, identify any consistencies with respect to adverse findings, look for patterns or trends in response between studies, and to summarize the experimental results at the end of the review (Refs. 2 and 3).

The data review proceeded in three phases. In phase I, all relevant toxicology studies were identified from FDA files and from the open literature. In phase II, 441 of these studies were obtained in hard copy and summarized. These summaries categorized studies as: (1) "Accepted," if on initial examination the study appeared to be reasonably complete; (2) "accepted with reservation," if the testing, on initial summary review, appeared acceptable but had some serious deficiencies interfering with interpretation of the data; or (3) "rejected," if there were inadequacies of the experimental design or data collection, or if dietary problems existed in the study that would prevent a valid evaluation. In phase III, 69 studies that either raised questions concerning the possibility of adverse effects or that appeared to support a conclusion that the irradiated food studied is safe were examined in detail and reported (Ref. 4).

Based on its examination of all the data, the Task Group concluded that studies with irradiated foods do not show adverse toxicological effects. However, the Task Group further concluded that traditional toxicological testing of food irradiated at doses below 1 kGy (100 krad) cannot be expected to provide meaningful answers to toxicity questions regarding such irradiated foods. The Task Group based this conclusion on several major reasons: (1) Nutritional imbalances created in the test animal fed high levels of irradiated or nonirradiated foods would tend to mask any potential toxicological manifestations; (2) the low concentration of any potentially toxic radiolytic products in the irradiated foods would prevent significant exaggeration of the amount of radiolytic products in a test diet; and (3) such toxicological testing is currently too insensitive to measure toxicity because the concentrations of URP's potentially present in the irradiated foods tested are simply too low. Based on its review of all studies, including those which tested food irradiated at doses more than an order of magnitude higher than 1 kGy (100 krad), the Task Group agreed with BFIFC's conclusion that there was an adequate margin of safety for foods irradiated below 1 kGy (100 krad). Hence, the Task Group also agreed that toxicology tests on foods irradiated at 1 kGy (100 krad) or below are not needed to support a conclusion that such foods are safe.

Based on the findings, rationale, and conclusions of BFIFC and the Task Group, FDA concludes that food irradiated at doses not exceeding 1 kGy (100 krad) is safe for human consumption. The agency further concludes that use of this level of irradiation should be exempt from requirements for toxicological testing because such testing would not be able to measure any toxicological properties of radiolytic products present in irradiated foods. In addition, the agency concludes that irradiation of dry or dehydrated aromatic vegetable substances is safe for human consumption at higher doses. The agency has determined that irradiation at doses no higher than 30 kGy (3 Mrad)

will be adequate to accomplish the intended microbial disinfection of dry or dehydrated vegetable substances. The agency emphasizes that although toxicological data may sometimes be helpful in evaluating the safety of irradiated foods, such data are not scientifically necessary for determining the safety of radiation for the uses and doses encompassed by this regulation.

In addition to studies available in the published literature, the U.S. Department of Agriculture (USDA) has made available through the National Technical Information Service (49 FR 40623; October 17, 1984) final reports of certain contracted animal toxicological studies of radiation-sterilized chicken and reports on chemical changes in food caused by irradiation. The agency has reviewed studies involving mice and dogs fed radiation-sterilized chicken meat and concludes that these studies do not show any treatment-related effects (Refs. 5 and 6). These studies are discussed in further detail in the responses to those comments which reference the USDA studies.

1. Radiolytic Products

1. Many comments expressed the opinion that the radiolytic products produced during irradiation would made the food harmful. Some comments stated that the radiolytic products are free radicals and that ingestion of these free radicals would be harmful. Other comments stated that the free radicals may later form toxic substances.

The agency disagrees that free radicals or toxic substances will be produced in food at unsafe levels under the conditions prescribed by this rule. The issue is not whether free radicals, hypothetically, can later form toxic substances, but whether the formation of a toxic substance is sufficiently probable to raise questions about the safety of the irradiated food. Although the generation and subsequent reaction of free radicals comprise the major route by which radiolytic products are formed, such reactions are also common during conventional food processing and storage operations. As was discussed above, substances that are chemically similar to radiolytic products are often formed or are present in foods that are not irradiated.

The important issue the agency must consider with regard to radiolytic products is the probability that a toxic radiolytic end product may be formed and whether such a product would be present in sufficient amounts to make the food unsafe. The agency has no evidence to cause it to change its position that the chemical differences between foods irradiated at the doses allowed by this regulation and nonirradiated foods are too small to cause concern about the safety of the irradiated foods.

2. Some comments expressed the opinion that irradiated foods are unsafe because ingestion of irradiated foods may result directly in toxic free radical and peroxide formation within the body.

The agency disagrees. Although irradiation produces free radicals as reactive intermediates in the food itself, the high water content of all fresh food provides a medium for their rapid degradation after irradiation. Thus, they are not likely to persist or be present at all in food by the time that food reaches the consumer. However, irradiated dry spices and seasonings are examples of foods in which free radicals are known to persist for long periods of time. Nonetheless, the manner in which these foods are used—as ingredients in other foods that contain water—provides a means for rapid dissipation of the free radicals, thereby precluding their ingestion.

While peroxides are sometimes formed in irradiated foods, they are also formed in foods that are not irradiated. The agency has no evidence to suggest that irradiated foods would be metabolized differently from nonirradiated foods and thus form unique or toxic free radicals or peroxides within the body. Therefore, the agency believes that concerns about the safety of irradiated foods as expressed in these comments are unfounded.

3. One comment stated that "[a]ny preservation of foodstuffs by irradiation at any dose may be unwise," and that gaseous oxygen from air gives rise to free radicals, peroxides, and hydroperoxides. The comment also stated that increased concentration of hydrogen peroxide ordinarily results from irradiation. The comment noted that "[t]he addition of hydrogen peroxide to food as a preservative has been prohibited in a number of countries, notably Japan, as a contributor to carcinogenesis."

The formation of detectable quantities of hydrogen peroxide, organic peroxides, and hydroperoxides during irradiation of foods in the presence of oxygen is well documented, and food processors normally try to minimize contact of their products with air during processing and packaging. Peroxides result from free radical chemistry, as discussed earlier, between oxygen and the primary radiolytic products from the carbohydrates, fats and oils, and water present in food. The potential biological consequences of the thermal degradation of the intermediate peroxides and their reactions with the multitude of food components have been addressed by a number of researchers (Refs. 7, 8, and 9).

FDA considered the potential carcinogenicity of hydrogen peroxide in its final rule permitting the use of hydrogen peroxide as an indirect food additive for sterilizing polyethylene food contact surfaces used for food packaging (46 FR 2341; January 9, 1981). The agency had specifically addressed a Japanese report of a bioassay of hydrogen peroxide performed with C57B mice in which the authors had indicated that the chemical may have caused duodenal cancer. Upon review and after consultation with the authors of the study, the agency stated that the evidence was insufficient to conclude that hydrogen peroxide is a carcinogen (46 FR 2341; January 9, 1981).

In that document, the agency also considered the issue of human exposure to hydrogen peroxide in food and concluded that milk packaged in materials sterilized by hydrogen peroxide would contain hydrogen peroxide at a level no greater than 100 parts per billion at the time of packaging. Moreover, after 24 hours, the hydrogen peroxide concentration would fall to about 1 part per billion, i.e., more than 99.9 percent of the hydrogen peroxide will no longer be present in the food.

Similar considerations leads the agency to conclude that any hydrogen peroxide produced during irradiation of fruits and vegetables or meats in compliance with this final rule would be rapidly degraded to negligible levels by natural enzymes and natural antioxidants in the food. Furthermore, any residual hydrogen peroxide, if present, would be considerably less than that encountered ordinarily in foods and environmental sources.

Organic hydroperoxides, formed by reaction of radicals resulting from reaction of oxygen with primary radiolysis products, are both thermally and chemically unstable and decompose to various aldehydes, ketones, alcohols, and hydrocarbons which constitute the primary radiolytic end products also identified as components of both unprocessed and conventionally processed foods. The yields of these substances formed under the conditions of this regulation are sufficiently low as to raise no concerns regarding safety.

Finally, microbiological studies that have reported toxic effects of irradiated aqueous sugar solutions in which peroxides and peroxo radicals are generated are discussed in paragraphs 21 and 22 of this preamble. The agency

has concluded that these studies are inappropriate models for assessing the safety of irradiated foods.

4. Some comments stated that no radiolytic products are unique and noted that the U.S. Army Natick Laboratory found no unique products in irradiated meats. These comments indicated that the term "unique" is misleading and should not be used.

The BFIFC report used the term unique radiolytic products (URP's) to describe substances produced in food during irradiation which have not been shown to be present in nonirradiated food. The BFIFC report recognized, however, that substances characterized as URP's may be normal minor constituents in the human diet that have simply not been detected through routine analysis of nonirradiated food.

As stated in the proposal, the agency agrees that some radiolytic products assumed to be unique may well be natural or common components undetected in nonirradiated food. However, it is impossible to demonstrate with absolute certainty that that will always be the case for all radiolytic products. Therefore, the agency cannot be certain that all radiolytic products are normal components of the human diet. To be prudent, the agency has assumed, for purposes of safety assessment, that some minor radiolytic products present may not be normal components of the human diet, and, thus, may be unique to the process. Based upon such conservative assumptions, the agency concludes that the amount of potential URP's would be so low as not to pose a safety problem.

5. One comment asked, "what happens to pesticide residues on produce when they undergo irradiation treatment? What are the health risks to humans?"

A pesticide chemical, like any other chemical component of food, will possess a certain level of sensitivity to ionizing radiation. The degree of sensitivity of a pesticide chemical to the primary ionizing energy and to chemical reaction with primary radiolytic products from other constituents of a food matrix will depend on the molecular structure of the pesticide. As is the case with other chemical components of a food, the total yield of radiolytic products from irradiation of any given pesticide will be a function of the amount of pesticide present, as well as its sensitivity to radiation.

The BFIFC estimated that the sum of all radiolytic products produced by irradiation at 1 kGy (100 krad) would be no more than 30 parts per million in food. This means the cumulative concentration of all radiolytic products from a pesticide residue would correspond to a concentration of less than 30,000 times smaller than the concentration of the pesticide residue itself. Because such low levels of pesticide residues are expected in food, the agency believes that the total amount of radiolytic products from a pesticide chemical that may be consumed from foods irradiated in compliance with this regulation at doses below 1 kGy (100 krad) will be virtually nil. Therefore, the agency concludes that the potential toxicity of each radiolytic product from a pesticide chemical residue on foods that are irradiated would be negligible and that such pesticide residues do not pose a hazard to health.

2. Spices

6. One comment stated that foods such as spices comprise more than 0.01 percent of the daily diet and that the proposed rule was inconsistent with BFIFC's recommendation that irradiation of foods constituting less that 0.01 percent of the diet be considered safe up to 50 kGy (5 Mrad).

The agency agrees that spices, in total, may constitute more than 0.01 percent of the daily diet. The agency has estimated a probable intake of dried spices and culinary herbs of up to 3 grams per person per day. For the general population, this constitutes 0.1 percent of the total diet of 3 kilograms.

The comment was apparently confused by terminology in the BFIFC report recommending that a "food class" which contributes 0.01 percent or less to the daily diet be considered safe for irradiation at doses up to 50 kGy (5 Mrad). The 0.01 percent in the recommendation was intended to refer to the dietary contribution of an individual spice (e.g., nutmeg or turmeric) as a "food class," not all spices as a "food class." Because radiolytic products from different spices are likely to be different, there is no reason to add the amount of radiolytic products from one spice, such as nutmeg, to another spice, such as turmeric, when evaluating safety. The intent of BFIFC's recommendation was not to set a precise dietary percentage limit of 0.01 percent but rather to acknowledge that the amounts of radiolytic products that would potentially be consumed from irradiated dried spices and seasonings are so small that such irradiated foods can be considered safe as ordinarily used. Neither the proposal nor the final regulation permitting the irradiation of spices at 30 kGy (3 Mrad) is inconsistent with BFIFC's recommendation.

7. Some comments on the proposed rule expressed concern that large amounts of irradiated spices and seasonings used by certain ethnic groups in their food would exceed safe consumption levels. The comments provided no information on which to base such a concern.

The agency recognizes that dietary patterns differ between groups of people and that certain groups consume more spices and seasonings than do other groups. Nevertheless, the agency has no reason to believe that any ethnic group will consume any irradiated spice or seasoning in amounts that would raise any safety concern, even considering dietary variations among ethnic groups. A single spice or seasoning would still be a minor ingredient in the diet. Moreover, as discussed in the previous response, the radiolytic products from one spice are different from those of another spice; therefore, their effects, if any, will not be cumulative.

8. The agency invited comments on the list of spices that is considered appropriate for irradiation. Comments recommended including those substances listed in § 182.10 *Spices and other natural seasonings and flavorings* (21 CFR 182.10), as well as other spices, seeds, and herbs commonly used as minor flavoring ingredients, and including teas and other vegetable seasonings. Some comments also stated that a specific list of spices was unnecessary and a phrase such as "herbs, seeds, and spices" should replace the individual listing of spices. One comment stated that to prohibit treating a spice mix because one minor ingredient is not on the list is not logical and suggested an alternative approach of granting overall approval to seasoning and flavoring substances currently considered generally recognized as safe because their safety would not be significantly changed by irradiation.

The agency disagrees that natural flavors should necessarily be included in the list and is not permitting the use of irradiation for natural flavors at this time. Natural flavors are components of food ingredients that have undergone some processing. Such flavors may be in solid or liquid form. The agency's conclusion that minor ingredients such as dried spices and seasonings may be irradiated safely was based on the fact that the amount of chemical change in the solid, dry state of a food is less than would occur when substantial portions of liquid are present and that dry ingredients would not support the growth of microorganisms that might survive irradiation. The agency has no

information from which to conclude that flavors in liquid form can be irradiated safely. Also, the agency has no information indicating that processed flavors require treatment for disinfection. Anyone interested in pursuing this matter further may do so by submitting an appropriate food additive petition.

The agency agrees that a specific list of spices and seasoning agents is unnecessary. Collective terms are used to describe different groups of these minor ingredients and such terms may be more appropriate than a detailed listing. Although herbs may be used for both culinary and medicinal purposes, a food additive regulation applies only to the irradiation of culinary herbs. Therefore, the agency is now modifying the regulation to permit irradiation of dry or dehydrated aromatic vegetable substances: culinary herbs, seeds, spices, teas, and vegetable seasonings.

9. Some comments apparently assumed that the proposed regulation would not permit irradiation of spice blends and requested modification of the regulation to permit such irradiation.

The issue is twofold: (1) Whether blends can be irradiated, and (2) whether the regulation authorizes the irradiation of enough ingredients to make the irradiation of commercial blends practical. The regulation does not preclude the irradiation of spice blends. The agency recognizes that the limited number of spices listed in the proposed rule would have prohibited blends containing other ingredients. As explained above, the agency agrees that the description of the substances that may be irradiated as dry or dehydrated aromatic vegetable substances should be more comprehensive than that listed in the proposed rule. In addition, salt and other adjuvants or minor ingredients (such as anticaking and free flow agents) may be used in a blend of seasoning substances. Under such limited conditions of use, the irradiation of these minor dry ingredients would pose no concern. Therefore, the agency is describing in this final rule the spices and seasonings in general terms and is explicitly authorizing the use of blends of aromatic vegetable substances, as well as salt and other dry foods ordinarily used as minor ingredients in such blends.

3. Other Minor Foods

10. One comment stated that color additives are important ingredients in the manufacture of processed foods, as well as drugs and cosmetics, and are used in minute amounts in the diet. This comment further stated that turmeric and paprika are color additives that are also included in the list of spices and vegetable seasonings that can be irradiated and suggested that the final regulation be expanded to include other listed color additives.

The agency does not agree that this regulation should include color additives. In preparing its proposed rule, the agency had not considered the ramifications of approving the irradiation of color additives. Such consideration would include whether specifications established for a color additive based on current manufacturing processes would still be adequate for the color additive after irradiation and what doses would be needed to accomplish the intended effects. Persons able to document the safe use of a source or radiation to irradiate color additives may submit a petition to the agency. The agency agrees that turmeric and paprika are both spices and color additives. However, their major use is as seasoning agents, and the agency sees no reason to preclude irradiation of these aromatic vegetable substances when they are also used as color additives (Ref. 10).

11. One comment stated that the rule should allow for the irradiation of dry enzyme preparations for microbial disinfection at a dosage up to 30 kGy (3.0 Mrad) because they are minor food ingredients.

The agency had not considered this specific use of irradiation in developing the proposed rule. However, the agency received a petition to treat dry enzyme preparations at doses up to 10 kGy (1 Mrad), and in the Federal Register of June 10, 1985 (50 FR 24190), the agency amended § 179.22 to permit this use. In this document, the agency is deleting § 179.22 and is incorporating that authorization for irradiation of dry enzyme preparations in new § 179.26(b). Persons able to document the safe use of a source of radiation at dosage levels higher than 10 kGy (1 Mrad) as authorized in new § 179.26(b) to control microbial contamination in dry enzyme preparations may submit a petition to the agency.

4. Destruction of Nutrients

12. Several comments stated that destruction of nutrients should be a concern in this rulemaking. The comments stated that many vitamins are light or heat sensitive, and that irradiation will destroy them. One comment stated that nutritional problems may develop for consumers because of nutrient loss when an entire class of foods is irradiated.

The proposal discussed this issue and explained that the available literature indicated that there are no nutritional differences between unirradiated food and food irradiated at levels below 1 kGy (100 krad). The minor ingredients allowed to be irradiated at higher doses are not sources of nutrients. Therefore, the agency believes it is appropriate to conclude that destruction of nutrients is not an issue in this rulemaking. There have been no additional data submitted to change this conclusion.

5. Selective Destruction of Microorganisms

13. One comment indicated that irradiation could contribute to increased aflatoxin contamination of foods. The comment cited a series of studies published in 1976 and 1979 by researchers from the National Institute of Nutrition of the Indian Council of Medical Research which reported that wheat irradiated at dose levels up to 250 kilorads showed a dose-dependent susceptibility to aflatoxin production (Refs. 11 and 12).

The agency disagrees that irradiation would contribute to increased aflatoxin contamination of foods. The studies referenced do not replicate actual food-handling practices. In the studies, the wheat was irradiated, autoclaved, and then innoculated with an aflatoxin-producing organism. The agency has no evidence that would lead it to conclude that food irradiated and stored under normal handling practices would show increased aflatoxin production. FDA does not believe that the results cited justify a modification of this rule.

14. Several comments stated that irradiation intended to eliminate one food hazard may affect the microbial spoilage patterns of food, thereby creating a new hazard. These comments expressed concern that *C. botulinum* spores would survive irradiation and would produce botulinum toxin without typical signs of food spoilage.

The agency agrees that this is a legitimate concern in some situations, but it does not apply to irradiation of dry foods or foods irradiated below 1 kGy (100 krad). Irradiation of food below 1 kGy (100 krad) will destroy few spoilage bacteria and thus will not change normal spoilage patterns. Furthermore, irradiation of minor ingredients at high doses, as allowed in this rule, would pose no problems because these minor ingredients are dry and dry foods do not provide a growth medium for *C. botulinum* spores.

15. Some comments stated that food irradiation may create or produce potentially harmful radiation-resistant bacteria, new bacteria, or viral mutants. One comment raised the possibility that mutated deoxyribonucleic acid (DNA)

fragments might be incorporated by bacteria, viruses, or cells of the human digestive tracts to create other harmful mutants.

Mutants produced during the irradiation of food are essentially the same as those that occur naturally. The only real difference is in the rate at which mutations occur. Radiation may increase the frequency of mutations and thereby increase the rate of evolution in bacteria or viruses that would occur otherwise through natural evolutionary processes. However, there is no reason to expect that the resulting mutants would be different or more virulent than those created in nature (Ref. 13).

Because bacteria are highly evolved organisms, well adapted to their environment, the vast majority of mutations would tend to be detrimental for the organisms. Mutant organisms that are more radiation resistant than their parents may survive and be present in an environment exposed to frequent sublethal doses of radiation. Such radiation-resistant bacteria, however, would be a problem only if irradiation were essential to produce a safe food. This is not the case and not permitting the use of food irradiation would not prevent such a problem from occurring.

Furthermore, the agency does not believe that such radiation-resistant bacteria or viruses, if they were produced, would be more resistant to other antibacterial agents. Although it is possible that specific conditions and indiscriminate irradiation might produce mutants, the agency concludes that the possibility that such mutants would be more virulent or more harmful is remote (Ref. 13).

There are only a few reports of genetic exchange between bacteria in the mammalian gut (Ref. 14). A few theories state that host cells may incorporate prokaryotic DNA, but it is not clear whether such genetic information is expressed. The agency sees no reason to prevent irradiation of food because of such speculations.

6. Toxicological Studies

16. Many comments claimed that it is FDA's first responsibility to ensure the absolute safety of all food produced and consumed in this country, not simply to make the process of production easier and/or cheaper for producers.

FDA agrees that its responsibility is to ensure that a food additive be demonstrated to be safe under the proposed conditions of use (21 U.S.C. 348(b)), but the agency does not believe that it was the intent of Congress, when formulating the act, that FDA ensure the consumer of absolute safety of all foods. Congress recognized that it would not be possible to determine with absolute certainty that no harm shall result from the intended use of a food additive. The Senate report stated: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." S. Rept. 2422, 85th Cong., 2d Sess. 6 (1958). As stated earlier, this is the standard of safety applied by FDA in its rulemaking for food additives.

On the other hand, the legislative history makes clear that Congress did not intend FDA to make regulatory decisions on the use of an additive based on an arbitrary opinion as to whether the additive should be used. Thus, the agency, in approving the use of a food additive, considers whether the food additive is safe and effective and not whether such approval will be beneficial to the producer of the additive.

17. One comment asserted that FDA's proposed regulation was illegal because it was not based on animal testing. While recognizing that neither the Food Additives Amendment of 1958 nor its legislative history specifies the exact types of tests that must be conducted to establish safe conditions of use of an additive, the comment claimed that a recurrent theme in much of the legislative history is the need for testing in animals to establish the safety of a particular additive.

The agency agrees that much of the testimony before enactment of the Food Additives Amendment of 1958 discussed animal testing of additives. This could be expected because most of the testimony about testing concerned direct food ingredients of unknown toxicity. Congress did not discuss how irradiation of food should be tested for safety. Furthermore, there is no indication in the legislative history that Congress expected every additive, whether an ingredient, a source of irradiation, or an incidental additive, to be tested the same way; nor does the act require such testing. Such a requirement would result in an unnecessary expenditure of resources. Consistent with this view, FDA has never required the same testing regimen for all types of additives.

FDA believes that the testing requirement envisioned by Congress was that there be sufficient testing to support the conclusion that there is a reasonable certainty of no harm from the expected use of the additive. The agency believes that any test that would not contribute to this conclusion should not be required. The agency has not required animal testing in the past under those situations where, by chemical or other testing and sound reasoning, it could conclude that the use of an additive was safe without animal testing. Therefore, FDA concludes that available animal test data are not necessary for determining the safety of those uses of radiation encompassed by this document. Animal testing is too insensitive to show an effect from irradiation of food at the doses allowed and, thus, would not contribute additional information to the evaluation of the safety of such uses.

Nevertheless, the agency reviewed all available animal studies to determine their adequacy and to evaluate the toxicological evidence. FDA's evaluation of these studies comfirms the agency's earlier conclusions that such data would not contribute further assurances of safety of foods irradiated in compliance with this rule.

18. One comment stated that food irradiation should be presumed dangerous until adequate scientific information is available for responsible decisionmaking and that FDA should make no decision until more information on hazards versus benefits of food irradiation is available.

For reasons discussed earlier in this section, the agency has determined that adequate information on radiation chemistry of foods is available to conclude that foods irradiated in compliance with this regulation are safe, and that the intended effects are achieved, thus complying with section 409 of the act.

19. One comment was concerned about the reliability of studies where animals were fed an abnormal diet and stated that results from these studies, positive or negative, may be misleading.

The agency agrees that standard toxicology tests where large percentages of the diet are composed of a single food, either irradiated or otherwise, may give results that could be misleading. The major difficulty in toxicological testing of irradiated foods has been to design tests that would provide useful and meaningful information regarding safety. It would be difficult to design a test that would exaggerate greatly the level of radiolytic products that will be ingested from irradiated food because, to accomplish this, the amount of irradiated food—the test substance that will be ingested—may also need to be increased. This increase in dietary intake may not be tolerated and may thereby become an added stress to the animal. A substantial change in diet may also create nutritional imbalances

among either macro- or micronutrients of the diet.

FDA believes, however, that useful information has been learned from those feeding studies where there has been some exaggeration of dose relative to that prescribed by this regulation. This information together with knowledge of the chemical changes that occur at low doses of irradiation is sufficient to establish the safety of food irradiated in accordance with this regulation.

20. One comment suggested that FDA should require animal feeding studies in which the animals are feed food irradiated at exaggerated doses to obtain an adequate safety factor.

FDA acknowledges that food additives have typically been tested in animals at levels that greatly exaggerate the proposed levels of use of the additive to establish an adequate margin of safety. This traditional method of establishing a margin of safety is inappropriate when the additive is a source of radiation. FDA has examined many early studies in which food fed to animals was irradiated at exaggerated doses to determine the effect of ingesting increasing amounts of radiolytic products. The agency noted that treatment of food with increasing doses of radiation can destroy essential components (e.g., nutrients) of the food or make the food unpalatable. These factors can confound experimental results.

Because these effects on food do not occur at the lower doses, exposure of the foods to exaggerated radiation doses would not in these instances represent a valid test for determining the safety of foods irradiated at the levels of use prescribed by this regulation. The agency has, therefore, concluded that exposing food to ever increasing doses of radiation as a means of increasing the amount of radiolytic products ingested is generally not appropriate.

21. A number of comments objected to approval of irradiation of any fruit or vegetable because of reports that irradiated sucrose solution caused toxic effects. The comments suggested that sucrose solutions would serve as good models for evaluating the safety of irradiated fruits and vegetables and that the reported toxic effects were reason to disapprove this use of irradiation.

The agency agrees that irradiated solutions of sugars have been shown to cause biological effects in vitro. Certain studies have shown: (1) Abnormal anaphase formation in bean root tips treated with sucrose solutions irradiated at 2 Mrads (Ref. 15), (2) decreased growth in carrot tissue cultures grown in sucrose solution irradiated at doses ranging from 0.05 to 2 Mrad (Ref. 16), and (3) increased revertants in *S. typhimurium* after incubation with irradiated solutions of sucrose and irradiated solutions of glucose and ribose (Refs. 7 and 17). (The agency points out that its use of the term "sugar" in this response is generic. Where appropriate, specific sugars are mentioned by name.)

The biologically active compounds formed during irradiation of sugar solutions in the presence of oxygen are predominantly dicarbonyl sugars produced by reaction of peroxy radicals with suger molecules. These dicarbonyl sugars can then be converted to *alpha, beta*-unsaturated carbonyl sugars which are also present in nonirradiated foods. The yield of biologically active carbonyl sugars will be less in irradiated complex food matrices than in irradiated simple sugar solutions because of reactions with substances such as metal ions and oxygen present in foods (Ref. 9).

The authors of the study using bean root tips (Ref. 15) postulated that the increased amount of abnormal anaphase was due to a drop in the pH of the irradiated sucrose solution. In a subsequent experiment reported in the same paper, the authors concluded that the low pH caused by irradiation of the sucrose solution alone was the cause of the mutagenic effects.

In feeding studies where sugars are present in a typically complex food matrix there is no increase in mutagenicity after irradiation. For example, direct irradiation of mango pulp to 20 kGy (2 Mrad) produced no mutagenic effect (Ref. 7). This study demonstrated that when a food containing sugars is irradiated, the food does not produce the same toxic effects that occur when these sugars are irradiated in simple solution. There is ample evidence (Refs. 7, 18, and 19) that the types and quantities of radiolytic products from irradiation of sugar solutions are not only dose dependent but are also dependent on specific conditions such as oxygen concentration and metal ions present in foods but not present in simple sugar solutions. Other studies on irradiated foods such as strawberries, dates, and mangoes likewise show no evidence of toxic effects (Refs. 20 through 26). The other studies that the agency reviewed regarding the toxicity of irradiated sucrose were of such poor quality that the agency does not believe that the data can be evaluated in a meaningful way.

The agency therefore concludes that irradiated aqueous sugar solutions are unsuitable models for predicting and extrapolating toxicity of irradiated foods. Therefore, the effects observed in these types of studies are not considered by the agency to be a reason for concluding that the uses of irradiation set forth in this regulation are not safe. The agency also concludes that there is no evidence that radiolytic products from sugars present in irradiated foods ause toxic effects to animals or humans.

22. One comment stated that a report in *Nature* magazine (Ref. 16) indicates that eating sugars irradiated at doses ranging from 0.05 to 2 Mrad can produce the same genetic changes in humans as exposure to irradiation itself.

The agency has reviewed this study and disagrees with the comment's interpretation of what the study found. Indeed the authors clearly did not reach the conclusions attributed to them by the comment. Furthermore, if humans or animals were irradiated at doses even 1,000 times lower than the levels used in this study, not only sterility but lethality would result within hours. On the other hand, humans and animals have consumed food irradiated at up to 4 Mrads (Refs. 27 through 32) without any indication of adverse effects of any kind. The study the comment referred to involved the effects of radiation on carrot tissue in liquid culture irradiated at 20 kGy (2 Mrads). This study and others concerning the effects of irradiation on solutions of sugars were discussed in the response to the previous comment.

The agency recognizes that irradiated sugar solutions have produced toxicity in vitro. The agency concludes, however, that irradiated sucrose solutions are unsuitable models for predicting and extrapolating toxicity of irradiated foods. Additionally, no evidence indicates that irradiated foods, including those containing sugars, will cause adverse toxic effects to animals or humans.

23. A few comments stated that a study involving hundreds of thousands of humans over 20 or 30 years is necessary before FDA can say irradiated foods are safe.

The agency has never required such long-term testing in humans to approve the use of a food additive and disagrees that such a study is necessary or appropriate. The agency recognizes that it cannot say with absolute certainty that any food, irradiated or not, is absolutely safe for all people under all conditions. The agency believes that the differences between foods irradiated as prescribed by this regulation and nonirradiated foods are so small, particularly compared to normal variations in the diet, that no effect is expected to be observed. The agency

believes that the substantial amount of available toxicological information supports the conclusion that the irradiation of food, as set forth below, is safe. Therefore, there is no basis for delaying for decades a decision to regulate food irradiation to conduct the type of study suggested by these comments.

24. Some comments also stated that many of the long-term toxicity studies on food irradiation were performed by Industrial Bio-Test Laboratories (IBT) and should, therefore, be considered invalid because much of the data generated by IBT had been falsified.

FDA agrees that studies containing falsified data performed by IBT should be rejected. All studies identified in the agency's review of available toxicological literature on food irradiation that had been performed by IBT were rejected. Much of the data compiled by IBT had been falsified or were proven invalid due to flaws in data collection, data reporting, and/or in experimental design. Thus the agency considers such data unacceptable to support safety.

25. Several comments stated that there are only a limited number of adequate chronic feeding studies on irradiated foods and that testing of the long-term health effects of consuming irradiated foods has been inadequate.

The agency has determined that because only minor chemical changes may result in food treated with low doses of radiation, animal feeding studies are not necessary to establish the safety of foods irradiated under conditions prescribed by this regulation. Therefore, it believes that the number of adequate chronic feeding studies on irradiated foods is irrelevant to its safety conclusion. The agency has evaluated those chronic studies that have been properly conducted and are considered to be adequate by current standards. None of those studies show adverse effects from the ingestion of irradiated food.

7. Alleged Adverse Effects

The agency reviewed 441 toxicity studies on irradiated foods (Refs. 2, 3, and 4). Forty-five of these studies dealt with subacute toxicity, 58 with subchronic toxicity, 126 with reproductive toxicity, 14 with teratology, 110 with chronic toxicity, and 102 with genetic toxicity or irradiated foods. Only 5 of the 441 studies reviewed (3 chronic feeding studies (Refs. 20, 33, and 34), 1 reproduction study (Ref. 35), and 1 combined chronic, reproduction, and teratology study (Refs. 36, 37, and 38) were considered by agency reviewers to be properly conducted, fully adequate by 1980 toxicological standards, and able to stand alone in the support of safety. The reports of these five studies indicate no adverse effects from the irradiated foods fed to test animals.

Although most of the studies were generally inadequate by present day standards and could not stand alone to support safety, many contained individual components which, when examined either in isolation or collectively, allowed the conclusion that consumption of foods treated with low levels of irradiation did not appear to cause adverse toxicological effects. Further, many of the studies were deemed useful for resolving certain questions. For example, if a potent toxic material were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological signs would be manifest in the studies reviewed. However, agency scientists have seen no such effects that present consistent patterns or trends of adverse effects that might be attributable to exposure to food irradiated at low dose levels. The agency, therefore, concludes that irradiation of foods as prescribed by this regulation is safe.

26. One comment referenced a book, "Consumer Beware" by B. Hunter, which stated that rats fed irradiated bacon and irradiated bacon and fruit mixtures showed increased mortality and an increased incidence of tumors. The author stated that the tumor incidence was increased and longevity was decreased.

Summaries of these studies were submitted in an early petition for sterilization of bacon by irradiation. FDA originally issued a regulation based on this petition (28 FR 1465; February 15, 1963). However, following evaluation of the complete reports of this study, FDA concluded that the sponsor had not met its burden for demonstrating safety (33 FR 12055; August 24, 1968) and rescinded the bacon regulations (33 FR 15416; October 17, 1968). Although previous reviewers asserted that the irradiated bacon studies may have shown adverse effects, the agency, after extensive reexamination of the study, now concludes that the claimed adverse effects cannot be substantiated because: (1) The study was of poor quality, (2) the numbers of animals examined were too small (three rats per group per generation) to have any statistical significance concerning tumors or longevity, and (3) the "total" incidence was only slightly increased in the low-dose group with no apparent dose dependence. Most national and international scientific bodies do not consider an increase in total tumors appropriate criteria indicative of a carcinogenic response (Ref. 40). The important consideration for determining if there is a carcinogenic response is whether there is an increase in the number of tumors at a specific organ site. The Armed Forces Institute of Pathology report (Ref. 39) on this study maintained that the tumors "showed no predeliction for any single organ." The numbers of animals at risk were too few to conclude that there was an effect on tumor incidence or longevity. If such effects had been caused by irradiated bacon, they should have been reproduced in the other irradiated feeding studies, including those the agency considers properly conducted (Refs. 20 and 33 through 38). However, such adverse effects were not observed.

27. One comment referenced a statement in the book "Eating May be Hazardous to Your Health," by J. Verrett and J. Carper that "[i]rradiation at high levels has been shown not only to severely destroy vitamins and minerals in food, but also to cause reproductive problems, a shortening of the life span and other complications in laboratory animals. In some instances—for example, in irradiated jams and fruit compote—cancer is a suspected result." The comment also stated that Dr. Verrett was a biochemist and researcher with FDA for 15 years.

The agency agrees that irradiation at high dose levels has been shown to destroy vitamins and other nutrients in food. As discussed in paragraph 11 of this preamble, however, destruction of nutrients is not a public health problem under the conditions of use approved for sources of radiation by this regulation.

It is not entirely clear which studies the authors were referring to in the statement from their book. The agency acknowledges that Dr. Verrett was an FDA employee during which time she reviewed many of the early petitions on food irradiation. The agency has reevaluated her reviews of the studies contained in these petitions. Judging from the irradiated foods mentioned in the statement quoted from her book and in the memoranda in the petitions, it appears that she is referring to two studies in which rats were fed a diet of (1) irradiated bacon and fruit compote (mixtures) (Ref. 39) and (2) irradiated pork, peaches, jam, carrots, and flour (Ref. 41).

The longevity and tumor (cancer) questions referred to in study 1 are addressed in paragraph 26 of this preamble. The agency has stated that an increase in "total" tumors is not indicative of a carcinogenic response by modern criteria for judging

carcinogenicity and the numbers of animals at risk were too low to conclude that there was either a tumor or longevity concern.

During its evaluation of toxicology data in 1982, the Task Group listed reasons for difficulty in evaluating the reproduction data from this study. The reasons include: (1) Inconsistent reporting of the numbers of animals used in each replicate experiment in several summary tables, (2) stillborn animal data not reported for every generation, (3) number of pregnant females not reported for all generations, (4) number of litters cannibalized only reported for the parental generation, (5) no indication given as to how or from which litters subsequent generations were chosen, and (6) replicate experiments not consistently identified in the summary tables.

In the second study (Ref. 41), the authors stated that there was a higher growth rate in the 2d and 3d generation animals and inferior breeding performance. Dr. Verrett was also concerned with reproductive and longevity questions in this study. FDA's reevaluation of this study cannot support Dr. Verrett's claims because the study was of very poor quality. The study pathologist specifically detailed many of the study's shortcomings and stated in the final report that "any conclusions resulting from this work should be drawn from the overall picture rather than the detailed studies of isolated aspects or organs" (Ref. 41).

The agency agrees with the pathologist's statement and has attempted to evaluate the overall picture referred to by the pathologist. As stated earlier, 5 animal feeding studies (Refs. 20 and 33 through 38) concerning longevity and/or reproduction (out of 441 toxicological studies reviewed) were considered by agency reviewers to be well designed, properly conducted, and reported. The reports of these five studies indicate no adverse effects to test animals fed irradiated foods.

The agency review included reports of 44 chronic studies, 60 reproduction studies, and 66 combined chronic reproduction studies. Although most of these studies have been considered less than adequate for a variety of reasons, the agency has been able to conclude from them collectively that no treatment-related adverse effects on the longevity of test animals or their reproduction were evidenced by these studies.

28. One comment referenced the report of a study (Ref. 42) in which statistically significant changes in the weights of ovaries and testes were observed when irradiated onions were fed to mice.

FDA has evaluated the report of this multigeneration reproduction study and notes that it was only an abstract from the World Health Organization (WHO) and has never been published as a complete report. The effects reported were a decrease in ovarian weight, significant when compared to both the normal control (no onion diet) and the onion control (unirradiated onion diet), and a decrease in testes weight significant as compared with the normal controls only. Histological examination did not reveal any particular changes in the ovary and testes of the group fed irradiated onions. No effects were observed on reproduction, fertility, or other parameters observed. In 1977, a WHO committee reviewed a draft of the manuscript and reported that because there were no observed abnormal histopathology changes or deleterious effects on reproduction, these organ weight changes, if real effects, were not regarded as being treatment related. Other reproduction, subchronic, or chronic studies on irradiated onions (Refs. 37 and 43 through 47) at comparable or higher doses of irradiated food administered to other animals did not report any changes in ovarian or testicular weights. These findings lead the agency to agree with the conclusions of the WHO committee.

29. One comment, citing a review paper (Ref. 48), stated that "when dogs have been fed irradiated egg solids, reproductive failure has occurred, and chicks and rats have died as the result of hemorrhage due to lack of vitamin K."

This statement has been taken out of context. The authors were actually referring to the nutritional imbalances seen in some of these irradiated food studies. The entire quote reads:

> Despite the fact that the experimental animals are provided with diets of known nutritional requirements for adequate growth and development, the high level of test food which is incorporated in the diets may present a completely unrealistic situation which can place a nutritional stress on the animals and result in nutritional imbalances. An example of this situation has been observed in feeding of high levels of irradiated egg solids to dogs where the interrelationship between biotin and avidin was found to exert a role in causing reproductive failure. A related example of difficulty which has been experienced in separating potential toxicity and nutritional adequacy of irradiated foods was the previously mentioned effect of radiation sterilization on vitamin K (antihemorrhagic factor) in certain foods, which resulted in hemorrhage and death in chicks and rats. Careful and detailed studies are necessary to elucidate the mechanisms involved in physiological abnormalities of this nature.

FDA agrees with the authors that nutritional imbalances resulting from feeding large amounts of a single food to animals confound the results of these studies.

30. One comment stated that polyploidy (chromosomal changes) has been shown as a toxic consequence in animals and humans fed irradiated wheat.

The agency does not believe that this is a correct statement. The agency is aware that in several experiments conducted by the National Institute of Nutrition (NIN), Indian Council of Medical Research, Hyderabad, India, the investigators claimed that polyploidy (chromosomal changes) was a toxic consequence in animals and humans fed irradiated wheat. A committee of Indian scientists critically examined the techniques, the appropriateness of experimental design, the data collected, and the interpretations of NIN scientists who claimed that ingestion of irradiated wheat caused polyploidy in rats, mice, and malnourished children. After careful deliberations, this committee concluded that the bulk of these data are not only mutually contradictory, but are also at variance with well-established facts of biology (Ref. 49). The committee was satisfied that once these data were corrected for biases which had given rise to these contradictions, no evidence of increased polyploidy could be associated with ingestion of irradiated wheat.

The agency agrees with the conclusions of the committee of Indian scientists that the studies with irradiated foods do not demonstrate that adverse effects would be caused by ingestion of irradiated foods.

31. One comment disagreed with FDA's conclusion that foods irradiated at doses below 1 kGy (100 krad) are safe and stated that there is little reassurance in the fact that unidentified radiolytic products are present in irradiated foods at low concentrations, particularly if single exotic molecules may be capable of causing carcinogenic chromosomal aberrations.

The agency recognizes that radiolytic products will be formed in irradiated food. Ionizing radiation results in the formation of unstable free radicals and other reactive chemical intermediates which normally undergo rapid reaction to form more stable molecules. Of the total radiolytic products formed, a small fraction may be assumed to be unique or "exotic." Radiolytic products and URP's have been defined both earlier in this section and in the BFIFC report (Ref. 1). Certainly some URP's will be formed

which are structurally atypical of parent food molecules. Such URP's may be free radical coupling products of lipid and protein-derived radicals, dimers, and cross-linked products. However, enzymatic hydrolysis of some of these compounds by normal digestive enzymes is expected to yield normal molecular subunits such as fatty acids, amino acids, monosaccharides, and normal metabolic products of these subunits which would be the same result as from the normal digestion of the original parent molecules.

If exotic molecules of the extreme toxicity implied by the comment were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological trends and patterns would be manifest in the studies reviewed. Because it has seen no consistent trends or patterns, the agency concludes that foods irradiated as prescribed by this regulation are safe.

32. One comment referenced a study submitted to FDA by USDA on fruit flies (drosophila) fed irradiated chicken. This study showed a dose-related decrease in offspring (Ref. 50), and the comment stated that this effect is consistent with chromosmal damage.

FDA notes that in the sex-linked recessive lethal study in Drosophila there was no evidence of mutagenicity. Additional data on fertility and fecundity were also included in the study, and a dose-related decrease in offspring was noted. Although there were fewer offspring in the groups raised on irradiated diets than in concurrent controls, the agency concluded that this effect could arise from a host of causes unrelated to reproductive toxicity, and is an unreliable indicator of an adverse reproductive effect. Mammalian data on reproduction are more relevant to humans, and these studies, as stated earlier, demonstrate no consistent patterns or trends indicative of a positive reproductive effect.

33. One comment referenced a study submitted to FDA by USDA and stated that mice fed radiation-sterilized chicken meat showed a significant increase in testicular tumors, increased death rate, increased kidney damage (glomerulonephropathy), and decreased survival. In addition, the comment implied that male dogs fed radiation-sterilized chicken had significantly lower body weights throughout adulthood than dogs fed a frozen control diet, and claimed that this shows toxicity of the irradiated chicken diet.

The agency disagrees with the comment that these studies demonstrate a treatment-related increase in testicular tumors. The studies involving mice and dogs fed radiation-sterilized chicken were carried out at Raltech Scientific Services (Raltech). These studies were initiated under the sponsorship of the U.S. Army and completed under the sponsorship of USDA.

The report prepared by Raltech scientists suggested the possibility that chicken irradiated at approximately 6 megarads produced testicular tumors in CD–1 mice in lifetime feeding studies (Ref. 51). Agency scientists have independently examined the histopathology slides to determine whether testicular tumors were induced by ingestion of irradiated chicken. They concluded that the total histopathological evidence did not support a treatment-related induction of testicular tumors (Ref. 5).

These data were also referred to the National Toxicology Program's Board of Scientific Counselors for peer review. The Board concluded also that the data do not allow the study to be categorized as one demonstrating a carcinogenic response in mice fed chicken meat treated with gamma or electron beam radiation (Ref. 6).

All mice fed chicken meat diets (both nonirradiated frozen chicken meat control diets and irradiated chicken meat diets) showed signs of extensive mineralization and glomerulonephropathy and decreased survival compared to mice fed chow control diets. After careful examination of the studies and comparison of data between the mice fed chicken meat control diets and the mice fed chow control diets, the agency concludes that the effects were due to the high protein content of the chicken diets rather than to the fact that some diets were irradiated.

The agency noted decreased survival in the female mice of the group fed gamma-irradiated chicken. However, because the decreased survival occurred only in one sex group, and the result was only marginally significant ($p=0.04$), the agency does not consider this effect to be treatment related.

With regard to the dog feeding study, the agency does not consider the body weight decrease to be of toxicological significance because of the nature of the protocol that was followed. The maximum quantity of diet provided for each dog was originally limited to 500 grams per day (approximately 300 grams dry matter per day). However, some dogs fed chicken meat diets (irradiated, frozen, or thermally processed) consistently consumed the entire daily ration and consequently had higher body weights than dogs fed chow control diets. This difference in body weights between the different diet groups is attributable to excessive caloric intake of the dogs fed chicken meat. Assuming that the dogs should maintain an "ideal" weight, the contract laboratory restricted the food intake for "selected" overweight dogs as required to initiate weight loss until acceptable body weights were obtained. The few dogs considered underweight were allowed to feed until their body weight increased to an acceptable level. Because the diet was manipulated in this way, the agency does not consider the changes in body weight to be treatment related.

34. Several comments referenced two Russian reports (Refs. 52 and 53) that found damage to kidneys and testes in rats fed irradiated feed. The authors reported dose-dependent histopathological changes in the kidney and testes of rats fed irradiated lab chow. The changes were claimed to be similar to those changes seen in human autoimmune disease involving these tissues.

FDA has found that information on critical details of the experimental design of the studies is either incomplete or missing. The reproductions of photomicrographs are unusable, and the numerical data are incomplete across dosage groups. There is no information on the survival rates of rats to the end of the experiment. The total number of rats actually examined for histopathologic observation is not stated nor is the scope of such observations. There is a general lack of incidence values and survival information that are critical for interpreting the findings in the kidneys and testes.

The agency notes that the authors had not published any previous studies in which rats were used as experimental models and, therefore, these authors may not have been familiar with common progressive nephrosis of the rat kidney. The qualitative description of the kidney changes reported is generally consistent with kidney disease commonly seen in aged laboratory rats. Many of the features of chronic progressive nephrosis (Ref. 54) common to aged rats are identical with the microscopic changes described in kidneys by the Russian authors. Without information on the comparative incidence and severity of the kidney lesions in all groups, the agency cannot verify that these reported effects are treatment-related, especially considering the inevitability of these types of kidney changes in rats as a result of old age.

FDA reviewed the kidney data in 11 chronic studies (Refs. 28, 33, 34, 55 through 62) in which rats were fed

various diets consisting of food or feed irradiated at various doses under a variety of conditions to see if it would be possible to confirm the findings of the Russian authors. An examination of these results revealed no findings or evidence of treatment-related kidney changes as were reported by the Russian authors. One of the 11 studies reviewed, which most closely resembled the Russian study (Ref. 28), had also investigated rats fed a diet consisting wholly of chow irradiated at both a lower (2 kGy, 0.2 Mrad) and higher (25 kGy, 2.5 Mrad) dose. The agency reviewed this study and found no evidence of treatment-related kidney changes as reported in the Russian study.

Further, the treatment-related kidney effects claimed by the Russian authors have not been reported in any other mammalian studies as an effect caused by ingestion of irradiated food. Also, data available on irradiation of animal feeds where the whole animal diet is irradiated have not shown comparable pathology (Ref. 27).

Based on the descriptions of the findings of testicular effects, FDA believes that such findings are probably not induced by radiolytic products in the irradiated diet. Extreme size and weight differences between right and left testes can arise from trauma (e.g., fighting) or may be present from birth. It is not clear whether some of the microscopic changes that are discussed affected both testes or were a feature of the smaller testes. FDA also reviewed 11 studies to verify the testicular lesions reported by Russian authors, and none of the studies reviewed revealed treatment-related testicular changes similar to those reported in the Russian reports. One of the 11 studies reviewed, which most closely resembled the Russian study (Ref. 28), found no evidence of treatment-associated testicular changes similar to those reported in the Russian study.

The agency concludes that, given the paucity of data from these two reports and the considerable, more substantial, evidence from other studies, the resuts of these Russian reports do not raise valid questions concerning the safety of food irradiated under the conditions of this regulation.

35. One comment claimed that three reports showed dominant lethal effects of irradiated foods (Refs. 63, 64, and 65).

The agency has reviewed these studies, and two of these three studies have been addressed (Refs. 64 and 65) in the response to paragraph 30 of this preamble. the third study (Ref. 63) claimed to have demonstrated an increase in preimplantation deaths. In this study, mice were fed 50 percent of their standard chow diet irradiated at a dose of 50 kGy (5 Mrad). There was no increase in postimplantation losses. Postimplantation losses, determined by counting dead embryos, are believed to be the most reliable and sensitive indicator of dominant lethality. The authors found only preimplantation losses, which are much less sensitive than postimplantation losses and merely a measure of total implants dead or alive subtracted from the total number. In addition to the possibility that results of the study could be spurious, any number of factors other than dominant lethality may cause preimplantation losses, such as a decrease in the number of eggs ovulated.

If these effects were real, one would expect to see some effect on postimplantation losses at a lower dose because postimplantation losses are a much more sensitive indicator than preimplantation losses, as mentioned above.

Although the findings reported may be statistically significant, the authors were uncertain as to what to attribute these results. They concluded that the most probable mechanism by which these effects could be produced would be via chromosomal aberrations. The studies necessary to establish an association between these effects and chromosomal aberrations were not conducted. Additional treatment levels below that conducted as mentioned above to detect postimplantation losses or examination of the 24 to 48 hour fertilized eggs could have provided better evidence of causality; but these studies were not conducted. Thus, although preimplantation losses were observed, FDA concludes that there is no biological significance to this observation because it was not reproducible. In three comparable studies, two in mice and one in rats (Refs. 66, 67, and 68), where 100 percent of the chow diet was irradiated with 25 kGy (2.5 Mrad) giving comparable radiolytic products as those found in Ref. 63, no preimplantation losses were demonstrated.

B. Labeling Issues

Under current regulations (21 CFR 179.22 and 179.24), several specified foods are permitted to be irradiated provided that the label bears the following statements: (1) "Treated with ionizing (or gamma or electron) radiation" on retail packages, or (2) "Treated with ionizing (or gamma or electron) radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments. In the proposal, FDA stated that it was interested in receiving additional comments discussing: (1) Whether FDA should require any type of label statement on food that has been irradiated; (2) if so, whether the statement should be required only on labels of food that has been irradiated (first generation foods) or also on the label of finished foods which may contain irradiated ingredients (second generation foods); (3) whether any required label statement should remain the same as that provided under existing regulations (i.e., "treated with ionizing (or gamma or electron) radiation") or whether some other phrasing would be more appropriate (e.g., "processed with ionizing energy"); and (4) whether consumers would be more misled by the presence of some type of retail label statement or by the absence of such a statement.

The labeling provisions of this final rule differ from that in the proposed rule and from the current labeling regulations as follows: This regulation requires that the wholesale label bear either the statement "Treated with radiation, do not irradiate again," or the statement "Treated by irradiation, do not irradiate again," and that the retail label bear the following logo:

along with either the statement "treated with radiation," or the statement "treated by irradiation." Throughout the remaining discussion in the preamble about the labeling provisions, the agency has used the terms "treated with radiation—do not irradiate again," and "treated with radiation," to represent both alternatives that the manufacturer may use in its wholesale or retail labeling in order to simplify the discussion. In addition to the mandatory language, the manufacturer may also state on the wholesale or retail label the purpose of the treatment process or expand upon the kind of treatment used. That is, the manufacturer may include in the labeling any phrase, such as "treated with radiation to control spoilage," or "treated with radiation to extend shelf

life," or "treated with radiation to inhibit maturation" as long as the phrase truthfully describes the primary purpose of the treatment. Similarly, the manufacturer may choose to state more specifically the type of radiation used in the treatment, i.e., "treated with x-radiation," or "treated with ionizing radiation," or "treated with gamma radiation," if more specific description is indeed applicable.

The agency recognizes that, because this is a new technology, manufacturers may want to use additional labeling statements as part of a consumer education effort. For example, in addition to the required language, the firm may wish to state that "this treatment does not induce radioactivity." The agency will permit such educational statements if they are truthful and not misleading to consumers.

In lieu of labeling individual items of unpackaged irradiated foods, FDA is allowing the required logo and label to be displayed to the purchaser as a point-of-purchase counter sign or card or on the labeling of the bulk container.

Half the comments specifically addressed the retail labeling issue, and over 80 percent of those comments urged that retail labeling be "required to prevent consumer deception." The remaining comments opposed any retail labeling of irradiated foods. Most comments, however, were in favor of some sort of labeling for wholesale packages of foods still in processing to prevent reirradiation.

In addition, the large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers. Moreover, several comments argued that irradiation of food altered the organoleptic properties of food, thereby reducing its nutritional value. These changes in the food, the comments asserted, make the irradiation of the food a material fact that must be disclosed under section 403(a) and 201(n) of the act. Because of these comments, FDA had decided to require that the label and labeling of food products bear the appropriate statements to inform consumers that the food has been irradiated. The agency emphasizes, however, that the labeling requirement is not based on any concern about the safety of the uses of radiation that are allowed under this final rule. Further responses to these comments are contained in paragraphs 36 through 49.

36. One comment stated that FDA did not have the authority to require a retail label statement on foods that had been irradiated because such labeling was not a prerequisite for safe use under section 409(c)(1) and (d) of the act. This comment argued that where safety is not at issue, FDA's authority to require special labeling is much less expansive. This comment also stated that if the standard for misbranding under section 403(a)(1) of the act is whether an additive affects organoleptic properties of food (i.e., taste, color, smell, or texture of foods), the presence of many additives now commonly used in foods should be highlighted on current product labels because most additives affect these qualities to some degree. This comment also stated that conventional food-processing methods also affect the organoleptic properties of food.

The agency is of the opinion that there is adequate statutory authority under sections 403(a), 201(n), and 409 of the act to require a retail label statement on foods that have been irradiated even though there is no concern about the safety of such treatment at the doses provided by this final rule. Section 409(c)(3)(B) of the act prohibits the approval of a food additive if a fair evaluation of the data before the Secretary "shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act." In this case, the standard for misbranding under sections 403(a) and 201(n) of the act is whether the changes brought about by the safe use of irradiation are material facts in light of the representations made, including the failure to reveal material facts, about such foods. Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.

Food ingredients, including food additives that have a functional effect in food, are required to be disclosed on food labels. Food additives such as aspartame that are present as ingredients in foods are required to be included on the ingredient labeling statement on the food's label. Therefore, the consumer is informed of the presence of these ingredients and the representation is not misleading.

The agency agrees that conventional food-processing methods also affect the organoleptic properties of food in material ways but in these cases the processing is either obvious to the consumer or conveyed to consumers through labeling or packaging. Canned foods have obviously been canned and frozen foods have obviously been frozen. Pasteurized milk is not obviously pasteurized but this fact is declared on the label.

Canning, freezing, and pasteurization are, of course, well-established processes with which the consumer is familiar. Whether information is material under section 201(n) of the act depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer. The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers.

FDA has historically required the disclosure of a food processing agent whenever it is material to the processing of foods. For example, flour is required to be modified by the term "bleached" if bleaching agents are used in processing and modified by the term "bromated" if potassium bromate is used in the processing of the flour. These requirements are part of the standard of identity for various flours (see 21 CFR 137.205).

There are many other examples where processing must be disclosed. Several standards of identity require label disclosure if the product has been enriched or fortified (see 21 CFR 137.305, enriched farina). Several standards of identity for juices require that the label indicate when the product is made from a previously concentrated ingredient (see 21 CFR 146.145, orange juice from concentrate). Orange juice must also be labeled pasteurized when pasteurization is part of the juice's processing (see 21 CFR 146.140, pasteurized orange juice).

Foods made in semblance of a traditional food must disclose the processing difference. Potato chips made from dehydrated potatoes, onion rings made from minced onions, and fish sticks made from minced fish are all required to disclose these material differences in processing.

The agency concludes that requiring a retail label statement that a food has been irradiated is consistent with the agency's statutory authority and current labeling practice.

37. Several comments argued that a retail label requirement was inappropriate because irradiation was used in place of chemical fumigants and FDA does not require that these chemicals be identified on the retail label. One comment stated that "there is no more rational basis for labeling irradiated foods (at the retail level) than for labeling pesticide residues present in agricultural commodities, indirect additives from packaging, flour and bread from fumigated wheat, or the

current fumigated spices themselves." Another comment pointed out that FDA has long held the position that nonfunctional secondary additives need not be declared on the label and that the policy codified at 21 CFR 101.100 should apply to foods that have been irradiated.

The issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception. As stated earlier, irradiation may change the characteristics of a food in a manner that is not obvious in the supermarket. Packaging materials and incidental additives such as processing aids that have no technical or functional effect in the food and thus do not ordinarily affect the characteristics of the food may be exempted under 21 CFR 101.100 from the normal labeling requirements under the act. Furthermore, Congress specifically exempted pesticide chemicals under section 403(1) of the act from a retail labeling requirement when the food has been removed from its shipping container.

As stated earlier, FDA believes that the irradiation of food is a material fact that must be disclosed. The agency recognizes, however, that the irradiation of one ingredient in a multiple-ingredient food is a different situation, because such a food has obviously been processed. Consumers would not expect it to look, smell, or taste the same as fresh or unprocessed food, or have the same holding qualities. Therefore, FDA advises that the retail labeling requirement applies only to food that has been irradiated when that food has been sold as such (first generation food), not to food that contains an irradiated ingredient (second generation food) but that has not itself been irradiated.

38. One comment stated that a retail label requirement would imply that there is a hazard involved in radiation processing and that such a statement would mislead the public about the safety of the process and have a negative impact on the development of this technology.

Although FDA recognizes the potential for consumer confusion, because there is no safety problem with food irradiated in accordance with this final rule, any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs, and the presence of a retail label statement should not deter the development of this technology. Consumer comments reflect a growing awareness of the process of food irradiation. Many consumer letters acknowledge that food irradiation, as prescribed by the proposed regulation, will not cause the food to become radioactive. The agency has also received comments stating that experiences in other countries, such as the Netherlands, demonstrate that consumers do not necessarily reject irradiated foods when they are properly labeled.

A recent Good Housekeeping Institute Survey seems to support this view (Ref. 69). In addition, elsewhere in this document the agency has made it clear that manufacturers have the option of providing additional labeling to describe the specific purpose of the treatment provided that such additional labeling is truthful and not misleading.

The agency has also concluded, however, that the original labeling terminology required by existing 21 CFR 179.22 and 179.24 may be overly technical and that the type of radiation being used is not necessarily meaningful to consumers and that the retail label would be just as informative if the required retail statement were "treated with radiation." The regulation has been modified accordingly.

39. Other comments suggested that the retail label statement be revised to state: "treated with ionizing radiation to prolong shelf life to ——— (insert date)."

As explained above, any confusion created by the terms "radiation" or "irradiation" required to appear as part of retail labeling can be corrected by appropriate consumer education programs. Recognizing that labeling itself is a valuable source of consumer education, FDA encourages optional statements to be included on the retail label that expand upon the kind of treatment used or the purpose of the treatment. Such additional explanatory language may be used whenever the additional language is applicable and not misleading.

For example, "treated with radiation to control insect infestation," "treated with radiation to inhibit maturation," and "treated with radiation to inhibit spoiling" are all examples of acceptable alternatives describing the purpose of the treatment if in fact the additional statements reflect the purpose of the treatment. "Treated with electron beam radiation" is an example of an acceptable expansion on the kind of treatment, if in fact an electron source was used. These optional statements would not only have an educational benefit, but would also avoid any possible mistaken inference by the public that the required labeling is a warning statement.

A manufacturer who wishes to label its product as "treated with radiation to extend the shelf life to ——— (*insert date*)" would, of course, be required to possess data substantiating that the radiation treatment would, in fact, extend shelf life until that date.

In addition, a manufacturer who finds that the terms "treated with radiation" or "treated by irradiation" are misinterpreted by a significant number of consumers may petition FDA for approval of alternative language, e.g., "freshness preserved by irradiation." However, the manufacturer would be required to provide adequate evidence demonstrating that the alternative language is both more readily accepted by the public and not misleading as to the nature of treatment as a form of radiation.

40. Several comments took the position that food irradiation is a food-preservation process and should be considered a process instead of a food additive, at least for labeling purposes. Those supporting this view stated that other food processes are not required to be revealed on the label and that food irradiation should be similarly exempt from label declaration. The comments also stated that a retail label statement is not justified on the basis of risk.

The agency agrees that irradiation uses permitted by this final rule are safe. The retail label requirements of existing 21 CFR Part 179 were based on misbranding considerations and not on food safety or health risk considerations. As has been explained before, section 201(s) of the act specifically includes a source of radiation as a food additive (21 U.S.C. 321(s)).

Nor is there any statutory provision that exempts processes from being declared on a food label (49 FR 5718) and the agency must examine whether the failure to declare such processing is misleading to consumers. In this context it is not relevant whether irradiation is considered a process in determining whether retail labeling is appropriate.

41. Most comments written in support of a retail label requirement for irradiated foods stated that the irradiation process has not been demonstrated to be safe, and that if irradiation treatment of food is permitted, the food label should inform consumers about which foods have been irradiated so that consumers can make informed decisions about the kinds of foods they buy.

As discussed elsewhere in this document, the agency has concluded that the irradiation of foods at a maximum dose of 1.0 kGy (100 krad) is safe when used to control arthropod pest infestation or to inhibit the growth and maturation of fresh foods. In view of this fact, the arguments in favor of a

retail label requirement, based solely on the grounds that the irradiated food is not safe, must be discounted.

42. Several comments in favor of a retail label requirement argued that irradiation of food altered the organoleptic properties of food and reduced its nutritional value and that these changes are material facts requiring disclosure under sections 403(a) and 201(n) of the act. The comments stated that consumers have a right to know whether such processing has taken place.

A food is considered misbranded under section 403(a) of the act if its labeling is false or misleading in any particular. In determining whether labeling is misleading, the agency must take into account the extent to which the labeling fails to reveal material facts in light of representations made about the food or consequences that may result from the use of such food (section 201(n) of the act). Therefore, the agency must decide whether the changes in the organoleptic properties of irradiated foods constitute a material fact or whether the information that a food has been irradiated constitutes information that is material to a consumer even if the organoleptic changes were not significant.

The agency agrees that irradiation causes certain changes in foods and that even small changes that pose no safety hazard can affect the flavor or texture of a food in a way that may be unacceptable to some consumers. Even those opposed to a retail labeling requirement agree that under certain conditions irradiation causes substantial changes in the organoleptic properties of some foods. Moreover, as discussed in the response to comment 36, irradiation may not change the food in any way that is visible to the consumer, so a label statement provides the only means of letting consumers know that a food has been irradiated. Thus, the absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed. Therefore, this regulation provides that the retail label contain a statement that the food has been irradiated.

43. The agency has also reviewed comments that argue both for and against the substitution of the term "ionizing energy" for the term "ionizing radiation" in the proposed wholesale labeling requirement and in any retail labeling requirement that was contemplated but not proposed. Most of the arguments for the substitution stated that they favored use of the term "ionizing energy" to reduce the problem of confusing irradiation with radioactivity and argued that use of the term "ionizing energy" would be less likely to be misunderstood by consumers. Other comments argued that both terms are likely to be misunderstood by consumers.

In view of the fact that the term "energy" could be confused with its more ordinary meaning as applied to foods, namely, a capacity of the food to provide caloric energy, the agency does not agree that substitution of the term "ionizing energy" would be less likely to be misunderstood by consumers. Furthermore, none of the comments offered any substantive evidence that one term would more likely be understood than another, either at the wholesale or retail level.

The agency does recognize that some population groups may harbor a prejudice against anything treated with radiation but is of the opinion that with the labeling flexibilities provided in this regulation, manufacturers will be able to overcome these prejudices as consumers become more educated about the process and the advantages this technology has over alternatives existing in the industry.

44. One comment suggested that the agency use the term "picowave treatment" in order to parallel the term "microwave treatment" that is commonly used for another form of food processing.

The agency gave careful consideration to the use of this term but it finally concluded that it should reject this suggestion because the term "picowave treatment" is not in common use in the industry or in the scientific community and would be neither more informative to the consumers than the label statement "treated with radiation" nor more understood by those in the food-processing industry. In addition, the microwave terminology is associated with complete cooking of the food which in no way parallels irradiation treatment of food as permitted by this final rule.

45. Several comments suggested alternative language for the wholesale label statement based on the assumption that the agency would permit reirradiation of a food provided that the total absorbed dose did not exceed the permitted amount. These comments suggested statements such as "ionization processed with a maximum of ——— kGy" or "processed with electromagnetic energy (or picowaves) or electron beam energy (as appropriate) in the range of 0.5 MeV to 10 MeV with a dose of ——— (blank to be filled in by processor)."

Elsewhere in this document the agency has addressed the issue of reirradiation and has concluded that multiple exposure of foods to radiation is inappropriate. Therefore, there is no need to discuss these comments.

46. A few comments suggested that the wholesale label statement be replaced by a code stamp that would reflect the pertinent information about the treatment similar to that now used for the place and date of production for canned foods.

The agency has rejected this approach because the purpose of requiring a wholesale label is to alert other food processors that a food has been irradiated. The code stamp currently used in the production of canned foods is informative only to the individual canner. Different firms use different codes for their own special tracking of food lots. For a code stamp to be useful at all, there would have to be a universal code used by all manufacturers. Even this approach, however, is unsatisfactory when compared to labeling because there is a greater chance for error in interpreting a code stamp than in reading a statement that the food has been irradiated.

47. A few comments suggested that the agency permit alternative language to be substituted for any required statement to reflect more accurately the type of processing involved. In place of the phrasing "treated with ionizing radiation," the comments suggested statements such as "treated with x-rays" or "treated with gamma radiation from cobalt-60" or "treated with electron beam energy."

In the **Federal Register** of January 7, 1987 (32 FR 140), the agency proposed that terms such as "processed (or treated) by x-radiation" and "processed (or treated) by gamma radiation" could be substituted for "processed (or treated) by ionizing radiation" at the option of the processor, whenever the more specific treatment was applicable.

The agency concludes that the option to describe the type of radiation should still be made available to food processors. The agency is of the opinion that it is in the public interest for labels to bear a statement that is as descriptive of the process as possible. Permitting these alternative labeling statements will also serve to educate the general public about the various types of treatment used by food processors.

48. Several comments recommended that FDA require a logo to represent "radiation" instead of a worded statement on the label of retail foods that have been irradiated. These comments pointed to the fact that there is a symbol used internationally to convey the fact that food has been irradiated. A comment from the U.S. Environmental Protection Agency (EPA),

although not opposed to the use of a logo to represent use of the irradiation process on food product labeling, expressed concern that the symbol that has been used internationally closely resembles EPA's official logo. EPA asserted that use of the symbol might cause consumer confusion about whether EPA had endorsed use of a product that carried such a logo.

The agency believes that the use of a logo in conjunction with a descriptive label of the process would serve to educate the general public that the logo and the label are synonymous. Thus, the agency is requiring that the label and labeling of retail packages of foods irradiated shall bear the following logo

along with the statement "treated with radiation." This logo derives from the symbol that has been used internationally to convey the fact that the food has been irradiated.

For irradiated foods not in package form, the required logo and phrase "treated with radiation" shall be displayed to the purchaser by other means as discussed elsewhere in this document. In addition, the label and labeling and invoices or bills of labeling shall bear the statement "treated with irradiation—do not irradiate again" when shipped for further processing, labeling, or packaging.

With industry uniformly using this logo in conjunction with the wording "treated with radiation" or "treated by irradiation" and an educational effort to inform consumers about the meaning of the logo, the agency has modified this rule to require 2 years after its publication only the use of the logo without the accompanying terminology. The agency will assess the need for the mandatory language to accompany the logo during this 2-year period. Any extension of the wording requirement will be established through notice and comment rulemaking.

49. Several comments argued that even if a retail label requirement were a part of the regulation that this requirement should not apply to fresh fruits and vegetables because such labeling was impracticable. Other comments simply asked how any retail label requirement would apply to fresh fruits and vegetables sold in bulk retail food stores.

The agency does not agree that retail labeling of fresh fruits and vegetables would be impractical. The final regulation as modified states that packaged fruits and vegetables include the logo and the statement "treated with radiation" on the label. For irradiated fruits and vegetables not in package form, the regulation provides three alternatives for meeting the labeling requirements. As an alternative, each item of irradiated food may be individually labeled. The agency has been informed that some companies plan to label each piece of irradiated food. The required information may be displayed to the purchaser with either: (1) The labeling of the bulk container plainly in view or (2) a counter sign, card, or other appropriate device bearing the logo and the term "treated with radiation" in order to inform the consumer that this product has been treated with radiation. This approach is consistent with the exemption provided in 21 CFR 101.22(e) for bulk fruits and vegetables that may have applied waxes or coatings and for processed foods sold in bulk without packaging.

C. Current Good Manufacturing Practice

FDA has issued general regulations regarding current good manufacturing practices (CGMP) (21 CFR Part 110) as well as specific CGMP regulations for some types of food (21 CFR Parts 113, 114, 118, 123, and 129) or food additives (21 CFR 172.5, 174.5, 182.1, 184.1). Such regulations are based on standard practices of responsible manufacturers in the industry.

The CGMP regulation for irradiated food could not be based solely on current radiation practices because of the lack of substantial experience with food irradiation. However, there has been extensive experience with other types of radiation processing (e.g., hospital supplies), and the industry has established standards in some cases. FDA considered both the experience and standard practices in the nonfood radiation processing industry and CGMP in the food industry in developing its proposed regulation for irradiated food and in evaluating comments.

In general, comments were supportive of the proposed provisions in § 179.25, including the proposed requirement for a scheduled food irradiation process, to establish a standard operating procedure specific to each food and radiation facility. Many comments supported recordkeeping requirements and emphasized the need for personnel training and FDA inspection.

50. One comment on proposed § 179.25(c) was concerned about the training that would be required of the "qualified person with expert knowledge of radiation processing" and what Federal or State agency would license or otherwise certify a radiation processing specialist who is needed to establish scheduled processes. Another comment suggested that FDA convene a panel of experts to develop a protocol for the establishment of scheduled processes for food irradiation instead of leaving it to industry experts. The comment also suggested that the Codex Standards and the Code of Practice for irradiated food be incorporated or identified as a guideline for the establishment of a scheduled process (Ref. 70). (These documents were developed by the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations, and the World Health Organization.)

The agency has no jurisdiction over the licensing or certification of radiation processing specialists. (However, see comments regarding the training of radiation safety personnel required by the Nuclear Regulatory Commission (NRC) in the section on environmental impact elsewhere in this document.) The manufacturer is responsible for choosing individuals who are qualified by appropriate scientific training and applied experience to ensure the integrity of the food irradiation process. FDA believes that there is sufficient incentive for food manufacturers to select qualified people and that FDA need not intervene. Therefore, each manufacturer is expected to select personnel having expertise and experience in the radiation processing of food and knowledge of the requirements of the particular facility. The specialist's work experience must be documented and must demonstrate training and experience in radiation processing of food. FDA believes that a background check for such personnel would be done in any case. FDA has no plans at this time to require the licensing of such individuals or to convene a panel of experts to develop a protocol for the establishment of scheduled processes. The agency agrees that the Codex Alimentarius Standard and Code of Practice is a useful guide but sees no need to require compliance with that code by regulation.

51. One comment on proposed § 179.25(d) asked if food processors who

use irradiated ingredients in their retail products are subject to the recordkeeping requirements of this regulation.

The proposed rule and this regulation limit the maintenance of records to the food irradiation processor. Therefore, a food manufacturer who uses irradiated ingredients in foods designed for retail trade is not required to maintain records related to irradiation treatment.

52. One comment on proposed § 179.25(d) requested clarification about the length of time that records must be maintained. The comment stated that some dry foods, such as spices, may have a very long shelf life that cannot always be predicted by the processor. Another comment suggested that records be maintained only 3 years.

The proposed rule would have required the records to be kept for a period that exceeds the shelf life of the irradiated food by 1 year. FDA agrees that this requirement is not clear and is amending this regulation to require that the indicated records be retained for a period of time that exceeds the shelf life of the irradiated food by 1 year, or for 3 years, whichever period is shorter.

53. One comment stated that the allowed uses of irradiation should be specified in sufficient detail so that Federal and State officials may accurately determine whether a processor is complying with the regulations. The comment suggested that FDA consider specifying sampling procedures to monitor whether a processor is complying with the regulations.

As explained in this document, irradiation of food at the permitted safe levels does not produce amounts of unique radiolytic products sufficient to be detected using conventional food sampling and analysis techniques. Nonetheless, the agency agrees with the comment that specificity of procedures is essential to ensure that radiation processing has been properly carried out. That is why this final rule lists the permitted uses of irradiation and requires that a processor have a scheduled process for each food established by a qualified person with expert knowledge of radiation processing. The scheduled process must specify a dose range that will ensure that the absorbed dose will achieve its intended technical effect on the food being irradiated. The final rule also requires that records be kept that include, among other things, evidence of compliance with the scheduled process, source calibration, and dosimetry. Moreover, these records are to be made available for inspection by authorized employees of FDA. The agency believes that this is sufficient information to determine whether processors are complying with the regulation.

54. One comment stated that no mention is made in the regulation regarding the role of State officials. The comment expressed concern about possible questions regarding State activities in the area. The comment said that State officials might be called upon to assist FDA in enforcing the final regulation and wondered whether the final regulation ought to specify whether State activities involving food irradiation processing would be preempted under the regulation.

The act contains no specific provision preempting the field of food irradiation. The test of whether a State activity is preempted by Federal law and regulations is whether the State activity conflicts with and stands as an obstacle to the Federal program. The comment appeared to be concerned about whether State inspections or other actions in support of this final regulation would be preempted by this regulation. FDA notes that State officials routinely assist FDA in inspecting certain facilities that are within their State in order to conserve scarce agency resources. The agency has, for many years, worked closely with the States through cooperative work-sharing agreements affecting compliance with the act and its implementing regulations. These cooperative efforts would further the goal of this regulation and would not be precluded under any preemption doctrine.

55. Some comments stated that a regulation requiring access only to records is not adequate to ensure compliance, and that FDA should also propose strict monitoring or some degree of official inspection.

The agency has authority to conduct plant inspections for all food-processing plants. FDA did not intend to imply that compliance would be determined solely by inspection of records. FDA officials will inspect food irradiation plants and will copy and review required records to assure that the processor is complying with these regulations. The agency would like to clarify that it considers inspection of records to include copying of the records for further review, and is, therefore, adding the words "and copy" after "inspection" in new § 179.25(e) for the same reasons stated in the proposal for records inspection requirements (49 FR at 5719) based on sections 409, 703, and 704 of the act. Thus, if a food manufacturer chooses to engage in radiation processing of food, FDA will consider that processor to have waived any objections to the agency's requirement of inspecting and copying pertinent records with respect to irradiated foods.

56. One comment stated that testing of food irradiation dosage is limited by the accuracy of the testing dosimetry. The comment stated that the regulation must provide methods for determining the absorbed dose which can be directly related to standards of radiation maintained by the National Bureau of Standards.

The agency agrees that the accuracy of the testing dosimetry is important. Assuring accurate dosimetry is a part of developing a scheduled process. Nevertheless, optimum procedures for dosimetry may change, and FDA does not intend to limit dosimetry to any one specific system at this time. FDA would consider irradiation of food without adequate dosimetry to be a violation of the current good manufacturing practice regulations.

57. A few comments requested that the regulation permit multiple irradiations of food provided that the maximum dose limitation prescribed by regulation is not exceeded. The comments argued that there are conditions where a second radiation treatment would produce a useful effect without exceeding the maximum dose. One comment stated that the Codex Alimentarius standard for irradiated foods does permit reirradiation of foods under limited circumstances.

The agency disagrees that the regulation should permit the multiple irradiation of foods for the following reasons:

(1) An irradiated food that is properly packaged and stored should not require further irradiation to be marketable. Irradiation processing of food is not to be used as a substitute for good food sanitation practices.

(2) Where a food is irradiated more than once, the cumulative radiation dose cannot exceed the maximum allowable dose prescribed in the regulation. The determination of whether those foods that are irradiated more than once are in compliance with the regulation would be difficult and impractical, if not impossible. Inspection of irradiation records alone to determine compliance would be inadequate. Records maintained by different irradiation facilities with respect to the reirradiated food would not be available for inspection simultaneously. Moreover, if a food were irradiated in a foreign country and subsequently irradiated in the United States, the absence of records from the foreign radiation facility would make a determination of compliance with the regulation impossible.

(3) FDA is aware of the Codex Alimentarius standard concerning reirradiation of foods (Ref. 70). The Codex Alimentarius standard does not permit reirradiation of foods, except for foods with low moisture content (cereals, pulses, dehydrated foods, and other such commodities), irradiated for the purpose of controlling insect reinfestation. This same standard, however, states that a food is not considered to have been reirradiated when: (1) The food prepared from materials, which have been irradiated at low dose levels, is irradiated for another technological purpose; (ii) the food, containing less than 5 percent of an irradiated ingredient, is irradiated; or (iii) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one installment as part of procesing for a specific technological purpose. In accordance with 21 CFR 130.6, FDA will review all food standards adopted by the Codex Alimentarius Commission. The agency is not required, however, to accept these standards.

Although the agency may, on its own initiative, propose adoption of a Codex standard under section 401 of the act (21 U.S.C. 341), any interested person may petition the agency to adopt a Codex standard (21 CFR 130.6). Because the agency has not proposed adoption of the Codex standard regarding reirradiation of foods as part of this rulemaking, this issue requires no further discussion at this time.

(4) The agency acknowledges that there could be certain circumstances where a useful effect could be produced by reirradiating a food without exceeding the maximum dose limitation prescribed by the regulation. However, as discussed earlier in this response, the agency believes that efforts to monitor compliance with this regulation through recordkeeping and records inspection would be difficult and impractical, and may even be impossible in certain instances. A further complication that would arise should reirradiation of foods be permitted involves the difficulty of complying with the labeling requirements prescribed by the regulation. Complex labeling at the wholesale level would be needed to ensure that the maximum cumulative dose absorbed by the food does not exceed the maximum dose limitation prescribed by the regulation. Wholesale labeling would also have to convey to what extent a previously irradiated food was treated. Furthermore, such cumulative doses would have to be the minimal radiation dose reasonably required to accomplish the intended technical effects. This minimal radiation dose would be very difficult to determine if it is administered in multiple doses. These complex issues would require careful consideration by the agency during a separate evaluation. For all of these reasons, the agency has concluded that reirradiation of food should not be permitted under this regulation.

58. Some comments questioned the need for a 5 million electron volt limit for x-ray sources and stated that this energy limit should be increased to 10 million electron volts.

The 5 million electron volt limitation for x-ray sources was based on data in an earlier petition and is consistent with recommendations of the Codex Alimentarius Commission. FDA has no data demonstrating the safety of sources operating at higher energy levels; accordingly, this regulation approves the use of x-ray sources of no more than 5 million electron volts. The agency will consider changing the limitation if data supporting the safe use of x-rays produced by machines using energy sources greater than 5 million electron volts are submited in a food additive petition.

D. Other Technical Effects

59. Several comments were opposed to food irradiation because it can theoretically affect the metabolic processes of fresh foods, and thereby conceivably make them less resistant to spoilage by various fungal diseases.

The agency recognizes that irradiation affects the metabolic processes of fresh foods and may sometimes make them less resistant to spoilage. Irradiation, like other processes, will not solve all food-preservation problems and will sometimes be impractical. Food processors would probably not irradiate food if irradiation causes the food to spoil more quickly or to become less marketable. In such cases, irradiating food would be contrary to the processor's self-interest. Because the practicality of using food irradiation makes this process somewhat self-limiting, the agency concludes that it need not restrict the irradiation of fresh foods merely because some foods may be unsuited to such processing.

60. Many comments requested that FDA take a more general approach to permit irradiation up to a dose of 1 kGy on any food for any purpose consistent with current good manufacturing practice. One comment stated that the rule should be extended beyond fruits and vegetables to mushrooms and pork. Several comments asked that the safe dose be raised to 1.5 kGy (150 krad). The comments stated that 0.75 kGy (75 krad) is necessary for maximum shelf life extension of papaya, and the 1.5 kGy safe dose would allow for some latitude in designing a commercial food irradiator. One comment stated that the term "insect control" may be too restrictive and suggested "pest control." Several comments stated that a maximum dose of 1 kGy is effective for trichinae control and for microbial control in some foods.

The agency intended the term "fresh fruits and vegetables" to include mushrooms, which are fruiting bodies of fungi. The agency now believes that the term "fresh foods" may more adequately describe foods such as fruits, vegetables, and mushrooms that are capable of additional growth and maturation but that may be treated with ionizing radiation to inhibit those processes. FDA is revising the regulation accordingly. In addition, the agency agrees that the term "insect control" may be too restrictive. Therefore, the agency is substituting the term "arthropod pests" to include insects, spiders, and mites, but to exclude pests such as bacteria, molds, mice, and rats.

Although the agency believes that the safety of food irradiation below 1 kGy (100 krad) has been established, the agency proposed to limit the use of food irradiation according to intended technical effect rather than simply by dose. This was done both to avoid indiscriminate use of irradiation and to aid enforcement of dose limits because there would be no reason to exceed the permitted dose for the allowed technical effects. For example, overtreatment of fruits and vegetables may adversely affect their marketability. Thus, exceeding the permitted dose would result in a substandard product. In effect, compliance occurs due to a self-limiting factor.

In the specific case of papaya, the agency believes that an adequate commercial radiation facility can be designed for papaya with the current limitation. Alternatively, the agency will review a petition to increase the maximum permitted dose for fresh foods.

The agency is aware that the permitted dose may also be somewhat effective for other uses, such as decreasing the microbial burden in meat, fish, and poultry. FDA did not propose these uses, however, because irradiating at such low doses would not be sufficiently effective for microbial control to be self-limiting. The agency stated in the proposed rule that it would consider other uses below 1 kGy (100 krad) if a petition supported by evidence that a specific technical effect can be

accomplished below 1 kGy (100 krad) and if an appropriate food additive regulation can be promulgated and can be enforced. The agency has received petitions for the use of irradiation to control trichinae in pork at doses below 1 kGy 100 krad). As discussed earlier in this preamble, the agency issued a final rule on July 22, 1985, in response to one petition to control *Trichinella spiralis* in pork (50 FR 29658). In this document, the agency is deleting § 179.22 and is incorporating that authorization for the irradiation of pork in new § 179.26(b).

61. One comment stated that FDA's proposed rule would have relatively little impact on solving the overall problem of food spoilage and contended that FDA is apparently seeking to avoid, delay, or otherwise shelve indefinitely the approval of irradiation at higher dose levels. The comment stated there is no reason for FDA's reluctance to proceed on its own initiative to approve food irradiation at doses above 1 kGy, including radiation sterilization of chicken. Other comments stated that FDA should permit doses up to 10 kGy based on the Codex Alimentarius standard.

FDA's traditional approach to issuing a food additive regulation has been to respond to a properly documented petition. FDA initiated this rulemaking to permit food irradiation because it believed that an agency-initiated rulemaking would be more efficient for those uses where the agency needs no further safety data.

Two considerations prevent the agency, at this time, from proposing a general regulation allowing higher doses. First, at higher doses, irradiation can significantly retard microbial spoilage without killing all spores of *C. botulinum*. Under some conditions, *C. botulium* can grow and produce a toxin that constitutes a health hazard. Based on current information, the agency is unable to prescribe safe conditions of irradiation at higher doses for foods that would ensure *C. botulinum* organisms would not develop.

Second, at the doses permitted in this regulation, the total amount of radiolytic products consumed is too small to be of concern, either because of low doses or because foods so treated are a minor part of the diet. Further, safety information from animal feeding studies is unnecessary under these circumstances. The proposal stated that FDA is reviewing a number of studies to determine whether foods that are irradiated at doses above 1 kGy (100 krad) can be considered safe without additional toxicological studies. As stated elsewhere in this document, the agency has reviewed these studies and found that five were acceptable by current standards. This data base is inadequate to support a broad decision that all foods may be irradiated safely at higher doses up to 10 kGy (1 Mrad).

Therefore, FDA does not intend to initiate further rulemaking on food irradiation based on the information before it at this time. The agency will, of course, continue to evaluate and respond on a case-by-case basis to all food additive petitions involving irradiation.

62. Several comments discussed using irradiation to control microbial contamination of animal feeds. One comment stated that the agency should consider the use of irradiation to treat all animal feeds up to a maximum dose level of 25 kGy (2.5 Mrad).

The agency agrees that irradiation of animal feeds to control microbial contamination could be addressed, but not necessarily as part of this rulemaking. Ralston Purina Co. filed a food additive petition (FAP 2198) (December 18, 1984; 49 FR 49181) proposing that the regulations be amended to provide for microbial disinfection of laboratory diets for rats, mice, and hamsters by radiation treatment. The agency responded to this petition in the **Federal Register** of February 19, 1986 (51 FR 5992). Any interested person able to document the safe use of a source of radiation to treat animal feeds may submit an animal food additive petition for that use under the provisions of 21 CFR Part 571.

63. One comment stated that the agency should permit the use of radiation to sterilize meals to provide a more nutritious and palatable diet for persons who require sterile meals.

The agency is considering a separate rulemaking to permit the investigational use of unapproved food additives under section 409(i) of the act (21 U.S.C. 348(i)). That issue is not relevant to the uses of food irradiation permitted under this regulation.

64. Several comments stated that there were other alternatives to irradiation for insect control or for growth and maturation inhibition of fresh fruits and vegetables and that, therefore, there was no need to permit food irradiation.

The agency agrees that there are other methods both for insect control and to inhibit the growth and maturation of fresh fruits and vegetables. However, the existence of such methods is not a reason to prohibit equally safe alternatives, nor does the act authorize FDA to arbitrarily limit the safe alternatives that are to be allowed. The agency believes that the marketplace should determine which alternative treatment method is used when safety is not an issue.

E. Packaging

65. One comment stated that FDA should consider the possible migration of toxic substances from packaging materials to food during irradiation. Several comments noted that the proposed rule does not discuss packaging materials and that this omission may create confusion with respect to § 179.45. In addition, one comment asked specifically whether the irradiation of bulk packaging materials such as fiber drums and burlap bags is permitted even though they are not listed in § 179.45. The comment questioned the need for § 179.45 and suggested, as an alternative, granting approval for irradiation of all substances that are currently generally recognized as safe as packaging materials.

FDA points out that all packaging materials or components of packaging material that may reasonably be expected to migrate to food must comply with appropriate regulations authorizing their use. Components of packaging materials that have been irradiated may migrate to food to a different degree than components of an unirradiated material.

There are two aspects to this problem: (1) A packaging material that is irradiated before food contact may degrade or undergo crosslinking or some other change so that it is significantly different from the nonirradiated material and (2) packaging material irradiated while in direct food contact may produce low modecular weight materials that might migrate into the food.

In the first case, the irradiated material may be tested to see whether it is suitable for use in contact with food and complies with appropriate regulations. If the irradiated material is still suitable for use and complies with the applicable regulations, no additional regulations are required. If the irradiated material no longer complies with applicable regulations, interested persons may submit a food additive petition to amend the regulations accordingly.

In the second case, volatile materials migrating into prepackaged foods during irradiation would not have been considered in evaluating whether the packaging material was safe for its intended use, unless the packaging material had been specifically authorized under § 179.45. Section 179.45 lists packaging materials that may be formed into containers for holding or packaging food intended to be irradiated

and which may be subjected to incidental irradiation during the radiation treatment of prepackaged foods. This regulation was issued in response to petitions for packaging materials used with food during irradiation in anticipation of expanded uses of food irradiation in the 1960's. Therefore, the agency disagrees with the comment that § 179.45 is unnecessary.

Section 179.45, however, does not list packaging materials that are generally recognized as safe (e.g., glass, wood, natural fibers) but which may exhibit different characteristics of migration to food during irradiation. FDA knows of no information on such materials during irradiation by which they could be generally recognized as safe. Therefore, FDA does not consider such materials to be generally recognized as safe when used in packaging that is irradiated in contact with food. The agency invites petitions to amend § 179.45 to include generally recognized as safe packaging materials and other packaging materials not currently in § 179.45.

The agency agrees that the failure to address packaging in the proposal may cause confusion. Because of the possible confusion, FDA is adding a new paragraph in § 179.26 clarifying the intended requirement that packaging materials containing food during irradiation must comply with § 179.45.

F. Public Education

66. Many comments stated that a need exists for a public education campaign supported by the government and industry.

The agency agrees that there is a need for public education in this area. However, the agency is responsible for ensuring that food additives including a source of radiation are safe; FDA has no proper role as a promoter of a specific food additive or food process. The agency believes that the primary responsibility for such educational activities remains with industry in this instance.

G. Impact Analyses

The agency stated in the proposed rule that existing safeguards in regulations issued by the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), the Department of Transportation (DOT), and FDA are adequate to ensure that there will be no adverse environmental effect. However, many comments expressed concerns about the environmental impact of this regulation. These comments can be separated into three categories: (1) Radiation safety within the facility (worker safety), (2) waste storage and disposal, and (3) transportation. FDA requested a response to these comments from OSHA (Ref. 71), NRC (Ref. 72), and DOT (Ref. 73) and has summarized their responses below.

67. Several comments were concerned with worker exposure and with plant safety and claimed that current safety standards are inadequate to protect workers employed in industries handling radioactive materials.

A facility using radioactive material must first obtain a license from NRC or the corresponding agency in an agreement State. NRC has informed FDA that in order for a firm to be licensed to possess and use radioactive material in an irradiator, the firm must file an application with NRC or the corresponding State agency. The information that needs to be submitted includes the training and experience of individuals responsible for the radiation safety programs, the training provided to persons who will work under the supervision of the responsible individuals, a description of the facility, the safety systems designed to protect personnel from exposure to radiation, and the radiation protection program.

NRC states that the regulatory "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators" (Ref. 74) provides guidance to potential applicants about specific details needed in an application for possession and use of radioactive material in an irradiator. The NRC staff reviews the application to determine that (1) the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life and property, (2) the applicant is qualified by training and experience to use the radioactive material for the purpose requested and in such a manner as to protect health and minimize danger to life and property, and (3) the program described will result in compliance with NRC's regulatory requirements. If the information provided in an application is satisfactory, a license is issued. After issuance, NRC conducts periodic inspections of irradiator facilities. In 1978 and 1979, NRC collected exposure data from all licensees. The average annual measurable dose for persons engaged in irradiation operations was 160 millirems. (The maximum permissible ionizing radiation dose for workers is 5,000 millirems per year.)

68. One comment stated that OSHA's ionizing radiation standard (29 CFR 1910.96) would apply to worker exposures from machine-produced radiations, but questioned the organization's ability to ensure worker safety.

In response to this comment, OSHA confirmed that its current ionizing radiation standard (29 CFR 1910.96) would apply to worker exposures to radiation from machine-produced sources. As in the past, OSHA will concentrate its inspectional resources on high priority problems, and will consider additional action should information develop indicating a need for concern.

69. Many comments were concerned about the safety of transporting radioactive materials, in general, and also argued that implementation of this regulation would lead to increased amounts of radioactive materials being transported.

Both DOT and NRC have responded to this comment. They stated that the transportation of radioactive materials is an activity which is highly regulated by both the Federal and State governments. Both DOT and NRC have regulatory requirements that govern all aspects of transportation in detail, from quality assurance in packaging to requirements for posting information that is clearly visible on transporting vehicles.

The overall safety of transporting radioactive materials was evaluated in the NRC report entitled "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" (NUREG–0170) (Ref. 75). The report concluded that the total risk from all transportation of such materials was acceptably low. NRC has concluded, after review of the subject, that the regulations are adequate to protect the public against unreasonable risks from the transport of radioactive materials (46 FR 21619; April 13, 1981). NRC believes such shipments can be made safely because licensees shipping radioactive material for use in food irradiators are required to comply with an NRC regulatory program.

Food irradiation sources are held in the form of welded, sealed sources and are transported in accident-resistant packaging. There has never been a release of radioactive materials from one of these packages in the United States as a result of a transportation accident, even when transporting powders, liquids, or gases. The transportation of sealed sources would make a release even more unlikely.

70. One comment stated that DOT, NRC, and the States are ineffective in their regulation of transportation of radioactive materials.

DOT disagreed and stated in a letter to FDA that the approach being used by NRC, DOT, and the States has been effective in ensuring safety.

71. One comment stated that the absence of effective regulations for transporting radioactive materials has prompted over 200 local communities to impose bans or restrictions on nuclear cargo transportation in defiance of Federal preemption.

DOT advised FDA that this is a misleading statement. DOT has no evidence that the transportation of radioactive materials has caused any safety problem. DOT pointed out that there may be a myriad of reasons behind these local restrictions, many of which may be unrelated to safety. Finally, the existence of local restrictions against the transport of radioactive material provides no evidence that there is or has been a safety problem associated with such transportation.

72. One comment stated that the history of monitoring transportation of radioactive materials leaves much to be desired. The comment cited incidents reported over the past 2 years where (1) sources were simply "lost" or were found by children in public, unrestricted areas; (2) sources were accidentally mixed with scrap metal; or (3) offsite contamination from radiation byproduct facilities resulted in widespread contamination. The comment further questioned what would happen when millions of curies are added to the commercial sector, if the Federal government cannot keep track of the approximately 17,000 sources in the United States.

DOT advised FDA that the references made by the comment to lost sources are misleading. The incidents referred to did not involve sources as large as those to be used in a food irradiator. Sources that have been lost in transit in the United States have been those of very low activity or empty packages that pose relatively small risks. High activity sources such as those used for food irradiation are transported in large, heavy packages which are not likely to be easily lost. Additionally, DOT's regulations require that the shipper of such packages notify the consignee when a shipment is made so that the consignee expects it and can take prompt action if it is not delivered on time. The comment about radioactive material being mixed with scrap metal refers to an incident in which a radioactive source was incorporated into steel made from scrap metal. This incident involved international licensing authorities and had nothing to do with domestic transport.

The agency has determined that the existing controls over the transportation of radioactive materials are adequate to ensure safety even when the number of radiation sources increases, as might be expected as a result of this rule.

73. Many comments expressed concern that an increased use of radioactive materials will lead to a corresponding increase in problems regarding proper disposal of radioactive wastes and possible environmental contamination.

Under NRC's regulations, sealed sources used in an irradiator may be disposed of by transfer to an authorized recipient as specified in 10 CFR 20.301(a). An authorized recipient could be the original supplier of the sealed sources, another licensee which is authorized to possess the sealed sources, or a facility licensed to receive and dispose of radioactive wastes.

In practice, a cobalt-60 sealed source is usually returned to the original supplier at the end of its useful life. Disposal of the sealed sources could be accomplished by transfer to one of the existing facilities authorized to dispose of radioactive waste materials. In the United States, these facilities are located in the States of South Carolina, Nevada and Washington. With respect to the cesium-137 capsules which the Department of Energy (DOE) has available for use in irradiators, DOE will lease the capsules to licensees and the capsules will be returned to DOE at the end of their useful life.

The agency believes that these measures are adequate to safeguard against possible environmental contamination.

74. Many comments were concerned that food irradiation might cause the formation of mutant pathogens. One comment stated that an environmental impact statement must be filed for this reason by the agency before further action is taken.

The agency considered the potential environmental impact of permitting food irradiation and concluded that an environmental impact statement was not required, and submitted this finding of no significant impact and environmental assessment to the docket for public review, as noted in the proposal. No new information or comments have been received that would alter the agency's previous determination. A response to the comment that mutant pathogens may result during food irradiation has been provided earlier in this document.

75. Various comments on the economic impact of this process stated that this process would provide consumers with a greater variety and quantity of foods than that now available because of quarantine restrictions or limited shelf life. Other comments stated that the process is expensive and thus would increase the price of food. Comments from industry stated that the costs involved in commissioning a facility would require a broader range of uses to make the operation financially viable.

The agency believes that the marketplace will determine whether irradiation of food is economically feasible. No information was provided to suggest that issuance of this final rule would pose an unacceptable economic burden on society.

III. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 19, 1986 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following sources referred to in this document are listed below. Documents with an asterisk (*) have been placed on display in the Dockets Management Branch (address above), and may be seen between 9 a.m. and 4 p.m., Monday through Friday. All the references not on display are available as published articles, reports, and books.

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V. Agency Action

FDA has evaluated over 5,000 comments as well as information already in FDA's files and concludes that the proposed use of ionizing radiation is safe and that the regulations should be amended as set forth below.

The agency assessed the impact of the proposed rule on current and future uses of irradiation technology (February 14, 1984; 49 FR 5714). This assessment demonstrated that the proposed rule was not a major rule as defined by Executive Order 12291.

Further, it was determined that the rule would not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act. In order to accurately reflect changes in this final rule made in response to comments, FDA has prepared a revised threshold assessment of the economic effects of this rule. The findings of this assessment do not alter the agency's previous assessment. Therefore, the agency hereby finds that this is not a major rule as defined by that Order and certifies in accordance with section 605(b) of the Regulatory Flexibility Act that the rule will not have a significant economic impact on a substantial number of small entities.

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (February 14, 1984; 49 FR 5714). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

Section 179.25(e) of this final rule contains a collection of information requirement. FDA submitted a copy of the proposed rule containing the same requirement to the Office of Management and Budget (OMB). This collection of information requirement was approved for use through March 31, 1987 (OMB Control No. 0910–0186).

List of Subjects in 21 CFR Part 179

Food additives, Food packaging, Irradiation of foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF FOOD

1. The authority citation for 21 CFR Part 179 is revised to read as set forth below and the authority citations under 21 CFR 179.21 and 179.45 are removed.

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 703, 704, 52 Stat. 1046–1048 as amended, 1057, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 373, 374); 21 CFR 5.10, 5.11.

§ 179.22 [Removed]

2. By removing § 179.22 *Gamma radiation for the treatment of food.*

§ 179.24 [Removed]

3. By removing § 179.24 *Low-dose electron beam radiation for the treatment of food.*

4. By adding new § 179.25, to read as follows:

§ 179.25 General provisions for food irradiation.

For the purposes of § 179.26, current good manufacturing practice is defined to include the following restrictions:

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of Part 110 of this chapter and other applicable regulations.

(b) Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use.

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods shall comply with § 179.45.

(d) Radiation treatment of food shall conform to a scheduled process. A scheduled process for food irradiation is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility. A food irradiation processor shall operate with a scheduled process established by qualified persons having expert knowledge in radiation processing requirements of food and specific for that food and for that irradiation processor's treatment facility.

(e) A food irradiation processor shall maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter, and shall make these records available for inspection and copy by authorized employees of the Food and Drug Administration. Such records shall include the food treatment, lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

[Collection of information requirements approved by the Office of Management and Budget under control number 0910-0186]

5. By adding new § 179.26, to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies not to exceed 10 million electron volts.

(3) X-rays generated from machine sources at energies not to exceed 5 million electron volts.

(b) *Limitations.*

Use	Limitations
For control of *Trichinella spiralis* in pork carcasses or fresh, non-heat-processed cuts of pork carcasses.	Minimum dose 0.3 kGy (30 krad); Maximum dose not to exceed 1 kGy (100 krad).
For growth and maturation inhibition of fresh foods.	Not to exceed 1 kGy (100 krad).
For disinfestation of arthropod pests in food.	Do.
For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes).	Not to exceed 10 kGy (1 Mrad).
For microbial disinfection of the following dry or dehydrated aromatic vegetable substances: culinary herbs, seeds, spices, teas, vegetable seasonings, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives. The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends.	Not to exceed 30 kGy (3 Mrad).

(c) *Labeling.* (1) The label and labeling of retail packages of foods irradiated in conformance with paragraph (b) of this section shall bear the following logo

along with either the statement "Treated with radiation" or the statement "Treated by irradiation" in addition to information required by other regulations. The logo shall be placed prominently and conspicuously in conjunction with the required statement.

(2) For irradiated foods not in package form, the required logo and phrase "Treated with radiation" or "Treated by irradiation" shall be displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. As an alternative, each item of food may be individually labeled. In either case, the information must be prominently and conspicuously displayed to purchasers. The labeling requirement applies only to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated.

(3) For a food, any portion of which is irradiated in conformance with paragraph (b) of this section, the label and labeling and invoices or bills of lading shall bear either the statement "Treated with radiation—do not irradiate again" or the statement "Treated by irradiation—do not irradiate again" when shipped to a food manufacturer or processor for further processing, labeling, or packing.

(4) The wording requirements of paragraphs (c)(1) and (2) of this section pertaining to the label and labeling of retail packages of food shall expire April 18, 1988, unless extended by the Food and Drug Administration by publication for notice and comment in the **Federal Register.**

Frank E. Young,

Commissioner of Food and Drugs.

Dated: March 29, 1986.

Otis R. Bowen,

Secretary of Health and Human Services.

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